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DR. ROBERT Q. MARSTON'S

SPEECHES AND ARTICLES

Volume II

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DR. MARSTON'S
SPEECHES AND ARTICLES

VOL. II

DATE	PLACE	TITLE	See TAB
8/4/70 Published?	U.S. Senate	1971 appropriation statement.	1
9/16/70 Published?	U.S. House of Representatives	Statement before Representatives on District of Columbia.	2
9/30/70 Published?	U.S. House of Representatives	Statement before Subcommittee on Interstate and Foreign Commerce.	3
10/5/70	Chicago, Ill.	Overview of federal support mechanisms. (Midwest-Great Plains Region of the American Assoc. of Medical Colleges) Speech 's final status UNKNOWN.	4
10/22/70	London, England	Biomedical research in the U.S.A., 1970. (Medical Research Council) Speech's final status UNKNOWN.	5
12/30/70	Chicago, Ill.	The outlook for biomedical research. (Symposium on "Science & the Federal Government, 1970," Amer. Assoc. for the Advancement of Science, AAAS)	6
2/13/71	Chicago, Ill.	Outlook for NIH support of medical education and research. (Assembly of the Assoc. of American Medical Colleges)	7
3/20/71	Chicago, Ill.	Biomedical research and the future. (Banquet address before the 49th General Session of International Assoc. for Dental Res.) Speech's final status UNKNOWN.	8
4/12/71	Chicago, Ill.	Outlook for NIH support of medical education and research. (Combined Councils of the FASEB)	9

DATE	PLACE	TITLE	See TAB
4/28/71 Published?	U.S. House of Representatives	Statement by Dr. Marston, Director, NIH, DHEW, on 1972 appropriation estimates.	10
5/1/71	Atlantic City, N. J.	Outlook for NIH support of medical education and research. (Assoc. of Professors of Medicine)	11
5/17/71	Wash., D.C.	A strategy for our Nation's health. (American Red Cross Convention)	12
5/17/71	Wash., D.C.	Maintaining the momentum of science. (recognition banquet of the Tomorrow's Scientists and Engineers Award Program)	13
5/25-28/71	Copenhagen, Denmark	A speech wasn't given because the facilities were unsuitable for the use of slides. (International mtg. of Med. Res. Council) Dr. Marston's travel report incorporates his remarks.	14
5/25-28/71	Copenhagen, Denmark	The background information on the organization and budget of the National Institutes of Health. (This was used as a FACT SHEET hand-out.) (International mtg. of Med. Res. Council)	14
6/9/71	Lake Placid, N.Y.	Environment for progress in Science. (Dedication of W. Alton Jones Cell Science Center)	15
7/31/71	Woods Hole, Mass.	The management of national research programs and implications of the cancer initiative. (Given before the OST Seminar on "Role of the Executive Branch in Biological Science."	16
8/6/71	Santa Barbara, Calif.	Progress and problems in heart and lung research. (Presented at the dedication of Goleta Valley Community Hospital's new heart and lung wing.)	17
10/1/71	Jackson, Miss.	Health careers. (Delivered at the Mississippi Health Expo I.)	18

DATE	PLACE	TITLE	See TAB
10/2/71	Grand Bahama Island	Background information on the organization and budget of the NIH. (Prepared for the Assoc. for Academic Health Centers.)	19
11/9/71	Cambridge, Mass.	Opening discussion--Sloan management seminar. (Alfred P. Sloan School of Management, MIT)	20
12/8/71	N.Y., N.Y.	Responsiveness of public science agencies to broad needs of society. (Rockefeller University)	21
1/11/72	Wash., D.C.	Health manpower education legislation & hospitals. (31st annual conference of the Maryland-District-Delaware Hospital Assoc.)	22
2/28/72	N.Y.C.	The background of the NIH position on ethical problems of clinical studies. (Presented at the 28th annual mtg. of the Amer. Fertility Society.)	23
3/25/72	San Francisco, Calif.	Inaugural remarks by Robert Q. Marston, M.D. (Given at the Symposium on Viral Hepatitis and Blood Transfusion at the University of California.)	24
4/18/72	Boston, Mass.	Biomedical research support today. (Cushing Oration, 1972 mtg. of the American Assoc. of Neurological Surgeons)	25

August 4, 1970
Senate

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Statement by Director, National Institutes of Health

on

1971 Appropriation Estimates

Mr. Chairman and Members of the Committee:

I am pleased to have the opportunity to appear before you again to testify about the goals, plans and needs of NIH for carrying out its responsibilities for Federal support of biomedical research, for education in the health professions and for biomedical communications.

During the past year there have been a number of important changes in the top level staff at NIH.

. . . Dr. Leonard Fenninger, who testified last year as Director of the Bureau of Health Professions Education and Manpower Training, has become Associate Director for Health Manpower which is a new position in the Office of the Director, NIH

. . . He has been succeeded as Director of the Bureau by Dr. Kenneth Endicott who has been Director of the National Cancer Institute since 1960.

. . . The new Director of the Cancer Institute is Dr. Carl Baker who has been with the Institute in various senior capacities since 1949.

. . . Dr. Thomas Chalmers, who was Assistant Chief Medical Director for Research and Education at the Veterans Administration, has joined NIH as Associate Director for Clinical Care Administration and as the Director of the Clinical Center.

. . . Mr. Storm Whaley has joined the NIH staff in the newly created post of Associate Director for Communications. Mr. Whaley was formerly Vice-President for Health Sciences at the University of Arkansas and director of its Medical Center.

. . . Dr. Carl Kupfer, who was chairman of the Ophthalmology Department at the University of Washington, is on board as Director of the new National Eye Institute which is now in full operation. The creation of the Eye Institute paves the way for greater emphasis on research on the prevention, treatment and cure of eye diseases and visual disorders.

Another area to which NIH is giving increased attention is research on diseases of the lung. As you know, we have brought together, for coordinated program direction in the National Heart Institute, various research programs on respiratory problems heretofore supported by other Institutes and we have changed the name of the Heart Institute to the National Heart and Lung Institute. This is not a piece of window dressing but a recognition of the fact that the responsibility of the Institute has been broadened in response to a growing national health problem and the emergence of scientific opportunities for productive research on lung diseases. The budget includes an increase of $2.5 million for research on pulmonary diseases.

Frankly, Mr. Chairman, we would much rather expand the role of an existing Institute than create a new one to meet new needs and opportunities. The missions of the ten existing Institutes, as defined in their enabling

legislation, cover the full spectrum of disease and biomedical research problems. The organizational framework therefore already exists for accelerating work on any disease problem or in any area of special scientific concern. In a time of many urgent competing demands for public funds, more can be accomplished if such additional funds as are available can be devoted directly to program objectives. The proliferation of Institutes is not only wasteful of resources--both in terms of staff and money--but it encourages a narrowness of focus that is not in the long-term interest of research on the interrelated problems of human disease.

The organization of NIH is already rather complex. As its activities are funded through 21 items in the bill, I should like to submit for the Committee's use--and for the record--an organization chart which has been specially prepared for these hearings. It shows

. . . the relationships of the various Institutes and Divisions to the functions of NIH;

. . . which Institutes and Divisions have separate appropriations and the amount requested for each in the budget; and

. . . the name of the Director responsible for the activity.

Before commenting on specific budget items, I should like to take a broad look at the responsibilities and programs of NIH. As you are well aware, the rapidly rising public demand for the readier availability, easier accessibility, higher quality, and lower cost of health services of

all kinds requires the rapid expansion of the national pool of suitably trained manpower. NIH has a major role in Federal support for the development of health manpower. It is one of our most difficult and most challenging tasks.

The institutions in which health manpower must be trained are plagued by a number of unsettling problems. They are faced with

. . . rapidly increasing costs, especially in teaching hospitals,

. . . competition for scarce faculty,

. . . restless students,

. . . public demands for greater community services, and

. . . unpredictable income from patients, insurance, and local, state and Federal governments.

All these factors militate against their willingness--and their ability--to expand their teaching activities or to experiment with new curricula and methods.

Despite these difficulties, there has been some heartening progress since the Health Professions Educational Assistance Act was passed in 1963. The number of students admitted to medical schools has increased by nearly 20% and reached almost 11,000 last September. The number of registered nurses in practice has increased by nearly 10% during the past three years. The construction programs have helped to build 12 new medical schools, 34 new schools of nursing, 6 new dental schools, 1 new school of public health and 2 new allied health training centers. Assistance has been given to 32 medical schools in serious financial straits. This year, scholarships have been given to 8,500 nursing students with serious financial need, representing 8% of total nursing school enrollments. More than 3,000 of these students come from

families making less than $5,000 a year. However, much more encouraging than these initial gains is the fact that all those engaged in training of health manpower are dedicated to the improvement of the health of the American people, that they recognize the national needs, and that they are confident these needs can be met.

The relationship of the NIH research programs to meeting these national needs requires some comment because it is often misunderstood. I commented briefly last year on the criticism that support for research has unbalanced the academic community and detracted from the performance of its educational function. I said then that the imbalance in the academic community is not due to too much research support but to the unfortunate fact that, until recently, this has been the sole kind of Federal support available. The clear and urgent need for comparable educational support is certainly not a consequence of the existence of research support. On the contrary, the need for educational support would have been acutely felt much earlier and would be even greater now if it were not for the existence of quite substantial research support.

The availability of Federal support for research during the past decade has had a tremendous and very healthy effect on the medical schools of this country. Substantial Federal funding of research made it possible to attract to their faculties highly competent physicians and scientists who derived much of their income from research but who were then, for a small investment of the schools' own funds, also available for teaching. This not only made it possible to increase the number of faculty members, despite small and static educational

funds, but it broadened the range of expertise of the faculty and, thereby, greatly enhanced the quality of the instruction provided. A notable feature of the development of medical schools during the past decade is the sharp increase in the proportion of full-time faculty which was largely made possible by the availability of research support. The influx of biomedical investigators into the medical schools on a full-time basis has, incidentally, also had a similar effect on the quality and the scope of the medical services rendered by the medical schools.

The deep involvement of medical schools in research is neither accidental nor ill-advised. Through the joint action of the Congress and the Executive Branch--in which this committee played a very prominent part--this country chose academic institutions as the principal place where research should be done. In most countries it is mainly done in quite separate research institutions. An incidental effect of this country's decision was to change--I should say, lift--the face of education in biology and medicine. Moreover, we chose to support research mainly through individual project grants, awarded on the basis of the individual merit of the applicant and his proposal through a widely praised review system relying on the scientific judgment of the applicant's peers and on the judgment of prestigious Advisory Councils concerning the proposal's relevance to the achievement of national research goals.

Most importantly, it should be recognized that the purpose of research support--and of the appropriations which make it possible--is to stimulate the search for knowledge and for the better treatment of disease. It was never intended to produce more doctors, dentists, or

nurses, or to provide a general subsidy for medical schools or other academic institutions. That it has resulted in the training of better physicians is, however, a secondary effect which should not be lightly discounted.

The heavy investment in biomedical research during the past decade has had a predictable result: The U. S. is now the acknowledged leader in this field of human endeavor. A significant relaxation of our efforts will, of course, have an equally predictable result. The direct and personal benefits which the people of this country have derived from this leadership are difficult to describe in simple terms. In fact, the practice of medicine has been revolutionized during the past twenty years as a direct result of research. Yet the unsolved problems of disease are so numerous and tragic that even the most notable advances seem disappointing in comparison. For example, the recent statement by Dr. Proctor Harvey, the president of the American Heart Association, that the death rate due to diseases of the heart and blood vessels among Americans under 65 is 20% lower today than in 1950 and that improved diagnosis and treatment has saved 51,000 lives since 1950 is overshadowed by the fact that cardiovascular disease nevertheless continues to be responsible for 54% of all deaths.

The fight against disease is a long, hard road. Quick victories cannot be expected. The investment in biomedical research must necessarily be a long-term investment. If we set our sights mainly on solutions that can be achieved in a year or two, we shall be frittering away our efforts and our resources on the easy edges of the hard-core problems of disease. A coat of paint can quickly make the house look better but it will never get rid of the termites.

A new dimension has been added to the national health problem by the rapidly accumulating--and, by now, quite overwhelming--evidence of the health risks inherent in alterations in our biological environment brought about by technological advances in other fields. A vast and diverse array of actually or potentially hazardous elements are involved, ranging from uncontrolled radiation to enzymes in detergents. One of the factors that has allowed this situation to develop--and one which makes it difficult to select appropriate remedies--is the lack of basic knowledge about the long-term effects on the human body of many of these new elements in the environment.

It is the special and unique role of the National Institute of Environmental Health Sciences to address itself to this lack of knowledge. Its intramural research and research-grant programs are focused on the biological effect of these hazards, singly and in combination, and particularly on the specific biological processes that are triggered or disrupted by exposure to various environmental pollutants. A knowledge of the impact of a suspected pollutant on the human body, the safe limits of exposure, a fairly exact determination of the body's reaction to it, and a clear understanding of the biological processes involved in this reaction are essential to the development of adequate and reasonable control measures. It is the purpose of this new Institute, now in its third year, to establish this basic information so that those, in other agencies and private industry,responsible for eliminating or controlling these hazards can do so intelligently and effectively.

The contribution of research training grants and fellowships to the health-manpower and health-service problems is even more direct than that of research grants. The primary purpose of postdoctoral training grants and fellowships is to maintain the momentum of research by training young investigators but they also play an important role in the training of medical specialists. At the postdoctoral level, research and education are truly intertwined. A knowledge of research methods is as essential to a medical educator as riding to a cowboy. While training grant and fellowship support have produced much of the medical school faculty, their output has fallen short of present requirements and is very far short of future requirements. The shortage of U.S.-trained faculty is evident from a recent survey by the Association of American Medical Colleges which shows that nearly 18% of the MDs on the faculty of U. S. medical schools--2,295 out of 12,867--are foreign-trained. The percentage for PhDs is considerably lower: 10%--or 666 out of 6,436--are foreign-trained. Overall, one medical school faculty member out of six received his training abroad. The AAMC points out that the equivalent of 10 medical schools are staffed by foreign-trained faculty.

The inadequacy of our physician-training efforts is illustrated by the fact that our dependence on foreign medical graduates to provide patient care has steadily increased. At the present time, one-sixth of

all physicians practicing in the United States are graduates of foreign medical schools. There are nearly 50,000 foreign medical graduates over 90% of whom are providing patient care. They make up 25% of the interns and 32% of the residents in our hospitals. In hospitals not affiliated with medical schools, there are two foreign medical graduates for every three interns graduated from U. S. schools.

Since I appeared before you last year, we have launched the Physician Augmentation Program, for which funds were included in the revised 1970 estimates. Under this program, an additional 500 first-year places will be provided in 29 schools starting with the 1970-1971 academic year. Over the next four years, the enrollment of these 29 schools will therefore have been increased by 2,000 students.

Dr. Endicott can discuss in more detail the status of the health manpower programs--all of which show some progress though not enough is yet being done.

One area to which, I believe, we should give much more attention is the training of what, for want of a better name, is frequently called allied health manpower. Many tasks in the health care field, ranging from the cleaning of teeth to the normal delivery of babies, can be competently performed by people with far less training than a full-fledged dentist or physician.

There are compelling reasons for giving serious consideration to a radical modification of our health-care system in this direction if we are to close the gap between needed health services and available manpower in a reasonable length of time and at a feasible cost.

The budget request for health manpower activities show an increase of $31.7 million. The major increases requested are:

. . . $14.6 million for project grant support for schools of medicine, dentistry, and osteopathy;

. . . $4.0 million for project grants for nursing schools;

. . . $3.3 million for project grants for allied health training.

On the basis of their relative priority, basic improvement grants for schools of veterinary medicine have been eliminated (a reduction of $2.7 million) and funds for project grants for graduate public health training have been reduced by $400,000. The net increase for institutional support is thus $19.1 million.

For student assistance, there is a net increase of $7.9 million. This includes an increase of $9.8 million for nursing scholarships and $2.2 million for allied health traineeships. The major offsetting reduction is a decrease of $3 million in the request for student loans in the health professions. The budget is predicated on the assumption that scholarships and direct loans will go for the most part to students from families with incomes below $10,000. It is expected that students from higher income families will be able to take advantage of the guaranteed loan program of the Office of Education for support or to secure private loans.

The budget request for the construction of health educational, research and library facilities is $126.1 million, the same amount as last year. It is entirely for educational facilities, as was also the case last year.

I am pleased to be able to report that the 1971 budget estimates for research reverse the downward trend of the past two years. There is a net overall increase of $61.8 million--or just over 6%--in the budget request for the Institutes and Research Divisions. The increases are for specific programs about which the Institute Directors, who are here, will be glad to answer questions.

The reduction in the level of research support due to the imposition of expenditure controls, by the Congress and the Bureau of the Budget, on top of the already tight budgets for fiscal years 1969 and 1970, is now having a delayed impact on the biomedical research community. We have abandoned our 1969 policy of trying to support as many project as possible with the funds available by renegotiating the amount of awards for existing grants. Successive renegotiations would quickly have reduced support to a level at which effective research was no longer possible. We believe that better progress will be made by adequately supporting the projects for which awards are made than by inadequately supporting a larger number.

As you know, increased costs have also forced us to phase-out 10 of the 93 general clinical research centers.

The increase of $61.8 million for the research Institutes in this year's budget results from the following major increases

. . . $22 million for research on cancer, especially the role of viruses;

. . . $12 million for heart and lung disease, especially arteriosclerosis and lung disease;

. . . $13 million for family planning and population research;

. . . $5.7 million for early childhood development and maternal nutrition;

. . . $6 million for dental research, especially dental caries, and

. . . $10 million for other important research areas.

Partially to offset the cost of increased research in these high priority areas, there is a reduction of $10.5 million--or about 20%--in the funds allocated to general research support grants. This represents an accommodation to fiscal necessities. We continue to regard this program as an extremely important component in the array of mechanisms for the support of biomedical research. Its objectives are

. . . to strengthen the research programs of the institutions;

. . . to encourage the recognition and support of emerging talent;

. . . to create central institutional research resources;

. . . to compensate for institutional program unbalances created by a national system of fund allocation oriented to disease categories;

. . . to stabilize, at least to a modest extent, the support of research-oriented faculty members during periods of otherwise unstable research funding.

A recently completed study of the program indicates that it has succeeded remarkably well in attaining its objectives, and that in so doing, it has advanced the Nation's research efforts significantly.

The restoration of Stone House, which is a permanent part of the facilities for the John E. Fogarty International Center for Advanced Studies in the Health Sciences, has been completed. The building is now in use. The first of the Fogarty Center's conference series was held there in April. The scholars-in-residence program is also under way. Funds are included in the budget to bring nine such scholars to the Center for a year but, as most of them cannot be absent from their regular posts abroad for more than six months, it will actually be possible to bring almost twice that many to the Center during the year. Three scholars are in residence now and four more are expected during the next six months. Plans for the new building for the Fogarty Center were somewhat delayed by an argument with the Fine Arts Commission but are now expected to be completed in December.

The appropriation for the current fiscal year includes planning funds for the construction of a building for the Lister Hill National Center for Biomedical Communications of the National Library of Medicine. Biomedical Communication is the indispensable link between those engaged in research, education and health service. The National Library of Medicine has long since outgrown the static role of a repository of information and now plays a vital part in the creation of a versatile and responsive national communications system. The budget request for NLM includes a small increase of $506,000.

The total budget request for NIH is $1,509,595,000. This is an increase of $92.9 million--or 6.6%--over the FY 1970 operating level, excluding funds carried over.

The items shown under NIH in the budget tables and justifications also include a request for $32.4 million for "scientific activities overseas". This is a department-wide program for the use of so-called counterpart funds --that is, foreign currencies accumulated and held by the United States under Public Law 480. The amount requested will be allocated as follows:

$10.4 million to NIH

$15.2 million to the Health Services and Mental Health Administration

$ 4.8 million to the Environmental Health Service

$ 2.0 million to the Food and Drug Administration

$ 8,000 to the Office of International Health

Last year, Mr. Chairman, I expressed the hope that circumstances this year would permit resumption of a more vigorous pace for the health programs for which NIH is responsible. I am glad that this hope was justified, at least in part. The budget requests now before you provide for significant increases in a number of important manpower and research programs. It is true that other programs are still at a rather Spartan 'maintenance' level. Overall, however, this budget will assure continued progress in attaining the two prerequisites for improving the health of the American people: better knowledge of the cause and cure of disease and adequately trained people to apply it.

TAB 2

STATEMENT BY

DR. ROBERT Q. MARSTON
DIRECTOR, NATIONAL INSTITUTES OF HEALTH
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

BEFORE

SUBCOMMITTEE NUMBER 4

OF THE

COMMITTEE ON THE DISTRICT OF COLUMBIA

UNITED STATES HOUSE OF REPRESENTATIVES

SEPTEMBER 16, 1970

Mr. Chairman:

We appreciate this opportunity of appearing before you to testify on H.R. 18568 and H.R. 18606, bills "To provide support for the health manpower needs in the medical and dental educational programs for private nonprofit medical and dental schools in the District of Columbia."

The bills would authorize the Secretary of Health, Education, and Welfare to make grants to private accredited nonprofit schools of medicine or dentistry in the District of Columbia, notwithstanding any other Federal funding. The grant to any medical school in any fiscal year would be equal to $5,000 multiplied by the number of full-time students enrolled in such school. In the case of a dental school, the grant would be equal to $3,000 multiplied by the number of full-time students enrolled.

The bills would authorize appropriations of $6,200,000 for fiscal year 1971, $6,750,000 for fiscal year 1972, and such sums as may be necessary for fiscal year 1973. The appropriation levels for the first two years seem to be related to computations for enrollments at the medical schools at George Washington University and the medical and dental schools at Georgetown University and do not take account of enrollments at the Howard University medical and dental schools.

In testimony before your Committee, representatives of George Washington University stated that "The financial needs of the schools of medicine and school of dentistry at George Washington University and Georgetown University are in such a critical stance that we come to the Committee of the District of Columbia, as a State government, for the support of the medical schools and dental school at these two universities."

The Department is well aware of the difficulties that private schools of medicine and dentistry are encountering in the face of spiralling inflation and increasing demands for increased enrollments and extensions of health services. While general assistance for health professions schools should be handled through the health professions educational assistance programs or whatever programs of this nature result from our current reappraisal in the health manpower training field, there is much to be said for providing special assistance to medical and dental schools in the District of Columbia area. In principle, we think the provision of financial assistance by States to medical and dental schools within their respective jurisdictions is commendable; and the provision of such aid for private schools in the District of Columbia would be consistent with this salutary practice of a number of the States.

Under the Health Professions Educational Assistance programs, assistance has been given to medical, dental, and other health professions schools for the construction of teaching facilities including both new construction and essential modernization and renovation; formula grant support for educational programs; student aid through both scholarship and loan programs; and special project support for a wide variety of educational purposes including expansion of enrollment, curriculum revision, and assistance to schools in serious financial straits.

Since fiscal year 1968, schools of medicine in serious financial straits have been receiving assistance under the Health Professions Educational Assistance special improvement grant and, beginning in fiscal year 1970, special project authorities of section 772 of the Public Health Service Act. (Special improvement grants were first authorized in fiscal year 1966, but no funds were available for this program until fiscal year 1968.)

The statutory limitation on the amount of a special improvement grant to any school was $300,000 for fiscal year 1968. The statutory limitation of $400,000 for fiscal year 1969 was removed by the Health Manpower Act of 1968 on the grounds that it was not possible at that time to predict the amounts that would be necessary to save some of these schools, and that the ceiling could jeopardize or thwart the achievement of goals which are necessary for the amelioration of existing critical health manpower shortages.

The Health Professions Educational Assistance special project authorities that were extended and amended by the Health Manpower Act of 1968, and which went into effect July 1, 1969, specifically provided for project grants to assist schools which are in serious financial straits to meet the cost of operations or to meet accreditation requirements. The broadened special project purposes also included expansion efforts and efforts to effect significant improvements in curriculums.

In fiscal years 1969 and 1970, substantially increased assistance has been given to schools in serious financial difficulties.

The George Washington University and Georgetown University medical schools and the school of dentistry of Georgetown University have been receiving assistance under these Health Professions Educational Assistance authorities. (See attachments 1, 2, 3, and 4 for summaries of awards to the respective schools.) In fiscal year 1970, under these authorities for institutional grants and student aid, George Washington University medical school received $704,188; Georgetown University medical school received $1,364,239 and its dental school received $756,949. In addition, the George Washington University medical school received a $15.3 million construction grant for its basic science building.

It is of particular interest in the context of these hearings that the amounts previously mentioned for institutional aid included special project grants to assist the schools in their financial straits. George Washington University medical school received for this purpose $248,100 in fiscal year 1968, $265,632 in fiscal year 1969, and $284,600 in fiscal year 1970, or a total of $798,332. For this same purpose, Georgetown University medical school received $120,968 in fiscal year 1969 and $219,346 in fiscal year 1970, or a total of $340,314. It is anticipated that both schools will file applications and will be eligible for such assistance in the current fiscal year. Assistance to each of these schools for continuation of projects already approved is projected (subject to the availability of funds) for fiscal year 1971 at $289,000 for George Washington University medical school; $1,634,000 for Georgetown University medical school; and $400,000 for Georgetown University dental school. The schools are also eligible to apply for supplemental assistance. (In fact, George Washington has just requested an extension of the date for filing its application for supplemental grant for fiscal year 1971.) It should also be noted that in 1970 Georgetown University medical school received a $680,206 grant under the Physician Augmentation Program (under the Health Professions Educational Assistance Special Project Authority) with a tentative commitment for continuation of the project for the following amounts for succeeding fiscal years--$1,312,000 for 1971; $1,819,000 for 1972; and $2,435,000 for 1973.

The Health Professions Educational Assistance authority is due to expire June 30, 1971. In appraising these programs and the current legislative authorities and developing our legislative proposals for submission to the Congress, you may be sure that serious consideration is being given to appropriate means of providing assistance to medical and dental schools in serious financial straits.

With the various studies we are conducting to develop our recommendations in the health manpower training field, we will also be studying methods for more precisely determining the cost of providing assistance to medical and dental schools in serious financial straits, both public and private.

The financial relationships of medical and dental schools are of an extraordinary complexity in keeping with the many functions they perform, and the different relationships they have with parent universities, their own or affiliated hospitals, public-local, State, and Federal programs for health services as well as programs of education and research, and their relationships with a wide variety of third-party payers for services as well as with those who provide private sources of income.

We are supporting cost allocation studies in 38 medical centers, including Georgetown University and George Washington University. The primary objectives of the studies are to develop methods to ascertain the costs of the respective functions and to determine the nature and form of the fiscal imbalances in these institutions. The development of these methods will allow a more accurate identification of these needs which are justifiably supported by Federal funding programs and those which should be corrected by alteration in the institutions' policies or administration or by support from local resources. When this type of information is in hand, we will be in a much sounder position to meet head on the issues raised by the legislation before us today.

To repeat: In principle, we think the provision of financial assistance by States to medical or dental schools within their respective jurisdictions is commendable. However, in the face of the dearth of information as to the actual fiscal situation of these institutions separately, or as compared with each other, or with other institutions similarly situated in the United States, we seriously question the specific approach taken in H.R. 18568 and H.R. 18606.

Therefore, we cannot now endorse as a reasonable approach a per capita payment by the Federal Government--based on total school enrollments--that cannot be related in a more persuasive way to public purposes to be served and to actual institutional needs. We

are particularly disturbed that the per capita level of support proposed appears to have been derived from calculations based on anticipated operating deficits. While we are not opposed to per capita formula grants as such, we would not want to establish--through the enactment of these bills--a precedent for that method of Federal deficit financing for medical and dental schools.

It should be noted, also, in evaluating the bills before us today, that the schools are asking the Federal Government for unconditional support which is significantly higher and without the attendant responsibilities required under per capita legislation in the several States providing similar assistance.

As you know, of the 49 private medical schools in the country (excluding those of the District of Columbia), 21--or 43%--receive no support from their States. Of the 8 States which assist the remaining 28 schools, NONE gives a straight per capita support for total enrollments without any conditions, as proposed in this bill we are considering today. The States which authorize fixed dollar per capita support have done so on the basis of per capita per STATE RESIDENT, or per capita per State resident with required enrollment increases, or--when not limited to State residents--per capita for new places or per increased enrollment. Only one State authorizes an amount per capita for total enrollments, and that State requires a 20% enrollment increase as a condition of eligibility for the assistance.

The remaining States which are providing operating assistance to private schools are doing so on the basis of negotiated subsidies which make it possible to assess the current financial situation of the institution and to assess also the appropriate and equitable role the State can play in assisting the operation of the institutions in light of all relevant factors.

Finally, Mr. Chairman, we have been concerned that the bills H.R. 18568 and H.R. 18606 would in effect cast the Department of Health, Education, and Welfare in the role of a State Government through its provision of direct support to these institutions.

We understand that a modification of the bills has been proposed by George Washington and Georgetown Universities to meet difficulties on the above point. Appropriations would continue to be made to HEW (as originally proposed), but HEW awards would be to the District Government rather than to the institutions directly. While this is an improvement, for the reasons indicated above we do not favor any proposal of this nature at this time. We have discussed this proposed legislation with the Office of Management and Budget and that Office concurs in our recommendation.

I will be happy to answer any questions you may have.

Attachment 1

HPEA Aid to

Georgetown University Medical School

	1965	1966	1967	1968	1969	1970
Basic Improvement Grants	$ ---	$87,379	$242,240	$255,500	$259,500	$259,500
Special Improvement Grants	---	---	---	0	120,968	219,346 1/
Special Improvement Grants (Physician Augmentation Program)	---	---	---	---	---	680,206 2/
HPEA Construction	(Grant of $2.0 million awarded in 1965 for replacement and expansion of basic science laboratories and library)					
Student Aid						
Loans:						
Capital contrib.	58,500	76,500	108,000	98,283	44,588	33,954
Revolving Fund	---	---	---	56,000	151,068	76,033
Scholarships	---	---	23,200	42,485	70,000	95,200

1/ Projected amounts of continuation of approved project in future years, subject to availability of funds, are as follows:

1971	$322,000
1972	400,000
1973	400,000

2/ Projected amounts for continuation of approved project in future years, subject to availability of funds, are as follows:

1971	$1,312,000
1972	1,819,000
1973	2,435,000
1974	2,600,000

HPEA Aid to

George Washington University Medical School

	1965	1966	1967	1968	1969	1970
Basic Improvement Grants	$ ---	$80,010	$223,128	$233,500	$238,000	$238,000
Special Improvement Grants	---	---	---	248,100 1/	265,632	284,600 2/ 3/
Special Improvement Grants (Physician Augmentation Program)	---	---	---	---	---	(No application
HPEA Construction	(Grant of $15.3 million awarded January 28, 1970, for multipurpose basic science building)					
Student Aid						
Loans:						
Capital Contrib.	87,017	141,962	276,037	205,037	128,388	65,732
Revolving Fund	---	---	---	30,901	69,132	34,781
Scholarships	---	---	21,200	39,202	59,875	81,075

1/ Of this amount, $190,248 was not spent.

2/ Total grant award was $284,000. Of this amount, $190,248 was carried over from FY 1968, so that the amount actually provided from 1970 funds was $94,352.

3/ Projected amounts for continuation of approved project in future years, subject to availability of funds, are as follows:

1971	$289,000
1972	289,000

HPEA Aid to

Georgetown University Dental School

	1965	1966	1967	1968	1969	1970
Basic Improvement Grants	$ ---	$ 77,203	$215,006	$228,500	$233,000	$233,000
Special Improvement Grants	---	---	---	0	157,396	344,196 1/
HPEA Construction	(Grant of $3.3 million awarded in 1966 for replacement and expansion of basic science and clinical facilities.)					
Student Aid						
Loans:						
Capital Contrib.	85,466	137,326	198,000	85,048 2/	53,973	29,771
Revolving Fund	---	---	---	103,353	138,787	66,582
Scholarships	---	---	21,200	38,473	63,600	83,400

1/ Projected amounts for continuation of approved project in future years, subject to availability of funds, are as follows:

1971	$400,000
1972	400,000
1973	400,000

2/ Does not include $27,599 awarded, not used, and later withdrawn.

Summary for FY 1970: HPEA Institutional and Special Project Grants and Student Aid Funds

	George Washington	Georgetown	
	Medical 1/	Medical	Dental
Institutional (Formula)	$238,000	$259,500	$233,000
Special Project	284,600 2/	899,552	344,196
Student Aid			
Loan:			
Capital Contrib.	65,732	33,954	29,771
Revolving Fund	34,781	76,033	66,582
Scholarships	81,075	95,200	83,400
Total	704,188 1/	1,364,239	756,949

1/ George Washington also received a $15.3 million construction grant award in FY 1970.

2/ Total award. Includes $190,248 carried over from FY 1968.

TAB X

STATEMENT BY

DR. ROBERT Q. MARSTON

DIRECTOR, NATIONAL INSTITUTES OF HEALTH

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

BEFORE THE

SUBCOMMITTEE ON PUBLIC HEALTH AND WELFARE

OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

SEPTEMBER 30, 1970

Mr. Chairman and Members of the Committee:

It is a pleasure to be here today to testify on S. 3418, a bill "To amend the Public Health Service Act to provide for the making of grants to medical schools and hospitals to assist them in establishing special departments and programs in the field of family practice, and otherwise to encourage and promote the training of medical and paramedical personnel in the field of family medicine, and to alleviate the effects of malnutrition, and to provide for the establishment of a National Information and Resource Center for the Handicapped.", and related bills.

Family Practice

Title I of S. 3418 would authorize a new five-year program of grants to medical schools:

(1) to operate separate departments devoted to teaching and instruction (including continuing education) in all phases of family practice;

(2) to construct facilities appropriate to carry out family practice training programs whether as a part of a medical school or as a separate outpatient or similar facility;

(3) to operate or participate in special training programs for paramedical personnel in the field of family medicine; and

(4) to operate or participate in special training programs for medical personnel to head departments of family practice or otherwise teach family practice in medical schools.

This Title would also authorize grants to public or private nonprofit hospitals which train medical students, interns, or residents:

(1) to operate special professional training programs (including continuing education) in family medicine for medical students, interns, residents, or practicing physicians;

(2) to construct facilities appropriate to carry out these programs whether as part of a hospital or as a separate outpatient or similar facility;

(3) to provide scholarships, fellowships, or stipends to interns, residents, or other medical personnel who are in need of such assistance to participate in accredited training programs in the field of family medicine and who plan to specialize or work in the practice of family medicine; and

(4) to operate or participate in special programs for training paramedical personnel in the field of family medicine.

For the purpose of making the grants to medical schools and to hospitals, the bill would authorize appropriations of \$50 million for fiscal year 1971, \$75 million for fiscal year 1972, and \$100 million each for fiscal years 1973, 1974, and 1975.

We are in full accord with the objective of encouraging and promoting the training of physicians and paramedical personnel to help to meet the needs of each patient for personalized care of his health needs. At a time of continuing increasing specialization and with a variety of types

of personnel and facilities often contributing to the care of a single patient, educational programs for health manpower at all levels must emphasize coordination and continuity for the health needs of individuals.

Comprehensive health care includes preventive, diagnostic, therapeutic, rehabilitative and health-maintenance services, and requires appropriate referral of patients for selected specialized and supporting services. This implies and requires effective coordination among physicians within the various specialties and with personnel in the nursing and allied health fields. It also requires adequate interpretation to the patient and his family of the nature and progress of the patient's illness and the services being recommended and provided in the context of the patient's expectations.

Continuity of care may be provided by several physicians working together in formal or informal association, with each member having access to the patient's records. Continuity may also be facilitated by the appropriate use of nurses and other allied health personnel under proper supervision, in situations where continuing attention by the same physician is not possible.

Methods of achieving the goal of comprehensive and personalized services for each individual are in a state of experimentation and change. A wide variety of terms are used to describe the kind of care or practice, or the type of practitioner, that is wanted: family practice, general practice, personal medicine, primary care, first-contact physician, generalist, comprehensive medical care are some of them. Many physicians

have been, of course, providing this kind of care right along. You are familiar with the manner in which general practitioners, internists, and pediatricians perform these roles.

In addition family practice is being increasingly recognized as a new medical specialty. The specialty has its own examining board, the American Board of Family Practice. The specialty requires a three year post-M.D. program of training consisting of one year of internship and two of residency. Like the specialties of pediatrics and internal medicine, it is patient-and family-oriented rather than disease-or-system-oriented.

The emergence of the new specialty of family practice provides one more evidence of the response to the need for personalized and comprehensive health care, and for encouraging concepts of personalized service and continuity of care across the board in medical training.

Increasing numbers of medical schools are teaching aspects of family care. In the last few years or so, substantial numbers of schools have recognized the need to develop a more concerted effort to give students, interns, and residents the opportunity to learn first hand more about the medical care of the patient as an individual, and as a member of the family, and about community resources that are available to augment the physician's efforts to provide effective care to all members of families.

We are very much interested in the development of programs that provide medical students with experiences in comprehensive health care and in family practice.

Under the Health Professions Educational Assistance Construction program we are assisting in the construction of medical schools and their teaching hospitals. Space for family practice activities (both the teaching and clinical practicum) is being constructed as an integral part of the teaching facility. This Committee is aware that we also administer authorities for construction of nurse training facilities and for allied health training centers. The Hill-Burton medical facilities construction program provides support for the construction and modernization of private, nonprofit medical facilities, including ambulatory care facilities of the type required for family medicine teaching programs. In addition, one of the priorities provided under the new Hill-Burton legislation is for projects for the construction of facilities which will provide training in health or allied health professions. In view of these authorities, the construction authorities proposed in this bill are unnecessarily duplicative and overlapping. We feel strongly that, particularly in the case of construction aid, it is more reasonable, feasible, and economical to provide general rather than categorical construction assistance.

In addition to the authority for the construction of teaching facilities under the Health Professions Educational Assistance Construction Program there is presently authority under the Health Professions

Educational Assistance Improvement Grants Programs for grants to medical schools for special projects to plan, develop, or establish new programs of education or modification of existing programs; to effect significant improvements in curriculums of such schools; to develop training for new levels or types of health professions personnel; to expand training programs; or to strengthen or improve programs of education. Health Professions Educational Assistance Institutional (Formula) Grants may also be used by the schools, at their discretion, for teaching purposes relating to family medicine.

A number of schools of medicine and osteopathy and their teaching hospitals have used, or have indicated their intention to use, at least a portion of their formula grants or their special project grants under the Health Professions Educational Assistance Program to support the teaching of continuity, primary, or family-oriented care through a variety of means. Some of these grants have been used to establish or strengthen departments of family medicine; others, to support family practice or continuity care teaching programs on an interdepartmental basis; and still others, across-the-board exposure of students to family care.

Among the medical schools that have been awarded special project grants for expansion of enrollment (including Physician Augmentation projects) under the Health Professions Educational Assistance Program, a number will give additional emphasis to the teaching of family medicine in the course of achieving the goal of increased output.

I should particularly like to address myself for a moment to the provision [section 761(a)(1)]of S. 3418 which would authorize grants to medical schools to operate separate and distinct departments devoted to the teaching and instruction in all phases of family practice. There is an implication in this provision that the only way for a medical school to emphasize family practice is to establish and operate a separate department of family practice. We question that implication. Our experience has shown that some schools are concentrating their educational program on the production of family physicians; other schools are developing family practice or continuity care programs on an inter-departmental basis, so that the concepts of family practice become an integral part of the teaching program of many departments. We feel that such efforts also have great potential and are making major contributions to both concepts and practice of family medicine. These contributions should also be recognized.

While a strong administrative mechanism for family practice teaching in the medical schools is desirable, a separate department is only one type of administrative unit. The AMA Ad Hoc Committee on Education for Family Practice, in its report entitled "Meeting the Challenge of Family Practice", has stated in discussing medical school administrative units for family practice:

"There are various ways in which this need--that is, for an administrative unit--might be satisfied: An academic department of family medicine is one way; another is the creation of a division of family medicine within a major department such as medicine; a third way might be the creation of an interdepart-

mental unit; and there might be other approaches which would serve satisfactorily in a given setting."

We are aware that the legislative flexibility for the support of family medicine activities through a variety of kinds of administrative units is provided in some of the other bills now pending before your committee, for example, H.R. 18716 and H.R. 13064. However, this legislative flexibility presently exists in the Health Professions Educational Assistance Special Project authority. (c.f. Section 772 of the Public Health Service Act.) This broader authority permits the support of a variety of administrative mechanisms within the medical school for carrying out family practice teaching programs and is especially suited to modification of training programs to coincide with changing patterns of organization of medical services.

In any event, we strongly oppose legislating the organizational structure within medical schools for teaching family medicine, especially when some schools are successfully developing such programs without separate departments.

With respect to the provisions of the bill for grants for special training programs for paramedical personnel in the field of family medicine, several other legislative authorities already exist under which such activities may be aided. Authority for Federal support of training of physician assistants and other new types of paramedical personnel has been provided under the Allied Health Professions Personnel Training authority for developmental grants (section 794 of

the Public Health Service Act). As you know, bills to extend and broaden this authority are presently in Conference. This authority has real potential for the preparation of new types of personnel to assist in providing the type of care toward which this bill is directed.

The allied health legislation would also provide authority for grants to a variety of agencies, institutions, and organizations for planning, developing, and establishing new programs of training para-medical personnel or effecting significant improvements in curricula. We feel that this legislative authority is sufficiently broad to cover the purposes of this bill and is the more appropriate vehicle for their accomplishment.

A number of projects involving the preparation of nurses to play a role in the provision of family-oriented medical care have been conducted under nurse training and public health training authorities. These have included, among others, projects to plan and evaluate experimental training programs for such clinical nursing specialists as pediatric nurse practitioners.

Mr. Chairman, with respect to internship and residency training, we must remember that the costs of salaries of interns and residents (and to somewhat less extent teaching costs for these training programs) are now met largely out of payments for patient services, including reimbursements for care rendered by such interns and residents under medicare, medicaid, and other third-party payment plans.

In view of the evolving character of the concept of family medicine, there are advantages to aiding activities in this field under broad, flexible legislative authorities such as those contained in the Health Professions Educational Assistance Act. This type of authority permits the support of alternative approaches to training in the provision of comprehensive and continuing care to individuals and families, pending further evaluation of the various mechanisms for educating personnel and organizing medical services in this field. It also allows aid for training in family medicine to be provided in conjunction with aid directed toward another purpose such as expansion of enrollment of medical schools.

The Health Professions Educational Assistance authority is due to expire June 30, 1971. The Department is in the process of developing its legislative recommendations for modification and extension of that Act and other health manpower legislation. Because of the close relationship between the family medicine activities proposed in S. 3418 and the Health Professions Educational Assistance Programs, we recommend against enactment at this time.

In any event, the Administration strongly opposes the enactment of educational categorical grant authorities such as those embodied in this bill which would duplicate authorities or mechanisms which already exist and under which the purposes of this legislation could be achieved.

Malnutrition

Title II of S. 3418 would authorize the Secretary of Health, Education, and Welfare to (1) make grants and contracts with medical schools, appropriate graduate schools, and nursing schools to establish courses dealing with malnutrition; (2) make grants and contracts with institutions and individuals for research into malnutrition; (3) establish special projects to provide practical training and experience for students of courses in malnutrition; and (4) provide fellowships and financial assistance to students to encourage and enable them to pursue studies and engage in activities in poverty areas relating to malnutrition.

Title II also directs that, in selecting educational institutions to carry out its purposes, priority be given to those located in poverty areas and authorizes appropriation of "such sums as may be necessary" to carry out these programs.

The Department is in accord with the basic objectives of Title II, which we understand to be (1) the creation of an effective force of field workers trained in malnutrition and nutrition to deal directly with this problem on the community level, especially in poverty areas, and (2) to encourage high-quality biomedical research in the area of malnutrition and nutrition.

The first objective is that of creating an effective force of field workers to deal directly on a community level with parents and children in vulnerable population groups, particularly in poverty areas.

For this purpose, Title II would support the establishment of courses in medical, nursing, and graduate schools dealing with malnutrition, its causes and effects, and its early detection and effective treatment. The students taking such courses would receive practical training and experience through special projects, particularly in poverty areas. In order to encourage enrollment in such courses, fellowships and financial assistance would be provided.

The Department feels that there is a distinct need for providing education on malnutrition on a *practical* level to enable workers emerging from such an educational effort to engage in down-to-earth community public health activities such as counseling mothers what foods to buy with a severely limited poverty budget, how to feed infants and preschool children, how to plan meals and budget expenditures for several days ahead, and the like. In this connection, the Department of Agriculture is devoting approximately $50 million to an outreach program to bring nutrition information to low-income families.

It is our judgment, however, that grants to the types of schools specified in this bill will not solve the problem of malnutrition among the poor. Even if we could assume that the people who most need help would come into contact with physicians and registered nurses--a not too likely prospect in present circumstances--the pressures to expand medical and nursing curricula and the demands of practice have produced a situation where physicians and nurses have necessarily become dependent upon specialists in nutrition to counsel patients and prescribe diets.

We have no reason to believe that adding nutrition courses to training programs of these health professionals would ease the pressures on their time that lead them to depend on nutritional specialists. We feel that the goal of enhancing community health activities in this area can best be met by focussing training on auxiliary personnel who are most likely to be dealing with nutrition problems on a day-to-day basis. One example which holds great promise is the development of community health workers operating out of the neighborhood health centers. These workers are in tune with the culture in which they are operating and can, after some training, be very effective in communicating the basics of good nutrition.

If we are to deal successfully with the problem of malnutrition, several elements of the problem must be taken into account. First, and most importantly, the poor are malnourished because they cannot afford the foods they need for a nutritious diet. Without the assurance of a reasonable minimum income, such as would be provided by enactment of the President's Family Assistance Plan, we cannot expect education to have much impact. Secondly, many people, rich and poor alike, are malnourished because they are ignorant of what constitutes good nutrition. In order to alleviate this problem we need to train the types of health workers who will be most effective in communicating the facts about good nutrition. Both the Nurse Training and Health Professions Educational Assistance Act improvement grant authorities provide the statutory mechanisms under which components of medical and nursing education may be strengthened.

We also call your attention to the fact that special training--both long- and short-term--in public health nutrition may be provided under the existing authority of sections 306 and 309 of the Public Health Service Act to professional health personnel including physicians, nutritionists, health educators, and social workers.

Although completely in accord with the second objective of Title II--support of research and research training in nutrition--the Department would point out that adequate authority now exists in the Public Health Service Act for all of the functions provided in this section, and more. These are now being discharged competently and extensively by the National Institutes of Health which is supporting a very substantial research and training effort pertaining to malnutrition and nutrition, both in the laboratories and clinics of several of the National Institutes in Bethesda and at numerous medical centers throughout the country. These activities cover the full spectrum of nutrition from fundamental studies concerning the metabolic and physiologic actions of the various nutrients and their requirements in man to practical, applied research aimed at alleviation of malnutrition and nutrition-deficiency diseases both in the United States and abroad. In addition, the NIH finances and administers a substantial and comprehensive program providing research fellowships and research training grants in nutrition. In the conduct of the very extensive nutrition programs of the NIH, the advice and assistance of many experts in the field are obtained continuously from the scientific staff of the National Institutes of Health and, on a consultative basis, from a very broad range of outside experts.

A special in-depth study in 1965 established the total expenditures of the NIH related to nutrition research at a level of $23,800,000. A more recent review indicates a similar level of expenditure for nutrition research in fiscal year 1968, as well as a total expenditure of approximately $2,100,000 for nutrition research training and $850,000 for fellowships. A substantial portion of this effort is related directly to nutritional deficiencies, malnutrition, and deficiency diseases and their various causes, and methods of diagnosis and treatment. Such levels of support are strong evidence that research in the field of malnutrition/nutrition is being given a very high priority by the NIH.

The Department feels strongly that Title II, in subsection (2), addresses itself to questions to which most answers already exist; in the instances where the relevant knowledge is as yet incomplete, these answers are being furnished continuously and are expected to be known in the near future. To use the language of the bill, the causes and effects of malnutrition are known, means for its detection are known, and the means for effective treatment of malnutrition are likewise known. The recent National Nutrition Surveys which pinpointed pockets of malnutrition among our poorest populations would indeed not have been possible were it not for the existing knowledge concerning the causes and effects of malnutrition and individual nutritional deficiencies, and methods for detection and diagnosis of such deficiencies.

No doubt the *primary* tool for nutritional improvement is financial improvement such as would be provided by the enactment of the President's proposed Family Assistance Plan. While the first objective of Title II appears to be the provision of better nutrition education for health

workers and members of the public, we believe the means chosen are not entirely appropriate and to some extent duplicative of existing authorities. The second objective of Title II, that related to biomedical research on malnutrition, though relevant, is being carried out broadly and effectively at present. The authorization in subsection (2) of the bill would be an unnecessary duplication of existing authorities.

In summary, we are in complete accord with the fundamental objectives of the proposed legislation. We feel that that part of Title II devoted to the education and creation of malnutrition field workers to work on the community level, particularly in poverty areas, is based on a true need but is somewhat misdirected. Rather than the establishment of a new categorical program of this type, we would recommend the continued development and enhancement of the ongoing programs of this and other agencies directed toward meeting the totality of the needs of our Nation's disadvantaged. We feel strongly that the second portion of Title II addressed to research in malnutrition is being carried out effectively under present arrangements, that special legislation for this purpose is not necessary and could result in a duplication of efforts.

National Information and Resource Center for the Handicapped

Senator Dole's bill, S.4002, to establish a National Information and Resource Center for the Handicapped, was passed by the Senate as Title III of S.3418. This proposal reflects the Senator's finding that disabled people, and groups interested in improving health, housing, recreation, rehabilitation and other services for individuals with handicapping conditions, have no single source of authoritative and complete information about governmental or other services available to them. In effect, this proposal would expand and broaden the scope of the authority for the Secretary of Health, Education, and Welfare which is contained in Section 7 of the Vocational Rehabilitation Act, as amended, to operate an information service and to make available to agencies, organizations and persons concerned with vocational rehabilitation, useful information on resources for various disabilities and other matters helpful in promoting the rehabilitation of handicapped individuals. The establishment of such a Center would be responsive to requests from many individuals and groups for guidance in finding and utilizing all available services and knowledge to meet the many needs of disabled people of all ages.

The information and data with which the Center would be concerned includes, but is not limited to, information about medical and rehabilitation facilities and services; day care and other programs for young children; education; vocational training; employment; transportation, architecture and housing (including household appliances and equipment); recreation; and public or private programs established for, or which may be used in, solving problems of the handicapped.

As the sponsors of this legislation have pointed out, a disabled person and his family have a special challenge they must meet each day -- that of accepting and working with a disability in such a manner as to become and remain as active and useful, as independent, secure and dignified as the disability will allow.

Many disabled young people and adults are cut off from normal experiences in going to school, and to church, participating in community activities, and in getting and keeping a satisfactory job. They must be helped, however, to utilize all available resources for their personal and social development. Some health and medical services are available in each State for children with mental and physical impairments. Many communities have special educational programs particularly designed for handicapped children. For those who do acquire some education and can seek employment, there is individualized help from the State-Federal vocational rehabilitation program. Services such as diagnosis and medical care, counseling, training, and assistance in finding employment are generally available from this public program. And in many communities voluntary programs aid many disabled children and older people.

For some handicapped people, a long period of care and training in rehabilitation centers and in workshops must be undertaken before the individual can be employed. For these and many other physically impaired people, there is great need for available information about community resources for outdoor recreation and other leisure time activities.

Information about technical schools and universities which can accommodate physically handicapped but intellectually able youth is often lacking. Available data are always incomplete and out of date. For the disabled who are going to school or trying to obtain and keep a job, accurate knowledge about which public buildings and which community plants and private office buildings are accessible and useable by them is of prime importance. They are also vitally interested in accessible public transportation--which bus lines, airlines or other modes of special transportation are able and willing to carry disabled people.

Many national organizations and community groups are now expressing concern about more economical and useable housing, recreation and transportation services for impaired people. In addition to ramps, wide doors and elevators, what architectural modifications will enhance self-care and independent use of the structure or facility? The National Conference on the Disabled and the Disadvantaged, sponsored by the Department and many national groups, highlighted the great demand for up to date information on research findings, the results of pilot and demonstration projects, and training and service efforts in the several States. The National Commission on Architectural Barriers recommended the establishment of information and technical assistance efforts to serve program developers, civic groups, research firms and others concerned with improving services for the disabled.

A major recommendation of the 1200 architects, engineers and civic planners who participated in barrier-free workshops of the American Institute of Architects last year dealt with sharing new technology and practice about the requirements of disabled persons.

In recent years many other commissions, task forces and committees working on single or multi-problem areas have referred to the necessity for communicating quickly and effectively new knowledge to physicians, rehabilitation practitioners and others engaged in the delivery of services to people who need them. These include the President's Commission on Heart Disease, Cancer and Stroke, the Department's Task Force on the Feasibility of a National Mental Retardation Information and Resource Center, and the President's Committee on Mental Retardation.

Earlier similiar needs and recommendations resulted in the formation of information exchanges in the education, scientific and medical fields. Examples are ERIC in the educational area, MEDLARS at the National Library of Medicine, and the Clearinghouse for Federal Scientific and Technical Data of the Department of Commerce. Services from these systems are available to researchers, planners, students, consumers of services, physicians and other professional groups, as well as the general public.

The Department suggests that a necessary and perhaps primary task of any new Center should be that of (1) helping to orchestrate the existing information systems, (2) filling in gaps in data by concentrating at least initially on one or more of the presently unorganized information areas referred to in the proposed legislation and (3) advising potential users about the resources of the existing and any new systems.

In summary, the Department supports this title of the bill. For reasons of proper administration, however, we recommend that implementation not begin until Fiscal Year 1972. In addition, we recommend that during the first year of the Center's operation, a complete plan be developed for utilizing pertinent data in ERIC, MEDLARS and other information and resource systems. Concurrently, a plan for obtaining, handling and releasing other new data, in accordance with a system of national priorities, should be developed.

Mrs. Kathleen Arneson, Special Assistant to the Commissioner of the Social Rehabilitation Service, is with me today and will be happy to answer any questions you may have on this part of the bill.

TAB 4

OVERVIEW OF FEDERAL SUPPORT MECHANISMS*

(Outline)

Robert Q. Marston, M.D.

I. Introduction and amenities.

II. The fiscal 1971 budget as applied to the medical schools.

A. Using past obligations to medical schools in relation to total NIH obligations, we have developed some estimates for fiscal 1970 and 1971:

	1970	1971
TOTAL	$580 million	$600 million
Research	310	340
Training	110	110
Construction	100	80
Institutional support	60	70

B. Explanation of the table.

1. Fiscal 1970 data are based on the 2-percent-reduction appropriation. Actual obligations to medical schools for 1970 have not yet been derived.

2. Fiscal 1971 is based on the budget now before the Senate. It is not known, of course, what the appropriation will be or what will be held back in reserve.

3. "Research" includes grants and contracts; medical schools received 45 percent of the fiscal 1969 obligations, and this percentage has been applied to the estimated research total to give the 1970 and 1971 projections. Contains

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*For presentation at a meeting of the Midwest-Great Plains Region of the American Association of Medical Colleges, Chicago, Ill., October 5, 1970.

general research support and DRR-BEMT programs.

4. "Training" includes all training awards--research training grants, fellowships, professional education support, and other manpower development. Medical schools received 62 percent of the fiscal 1969 allocations for these purposes.

5. Obligations for "Construction" were obtained from BEMT.

6. "Institutional support" is based on BEMT distribution to medical schools as shown in the 1971 President's Budget.

III. Other bills in Congress relative to medical research and education. (See attachment.)

IV. Looking ahead, what are the broad options for the medical schools?

A. In the research area, there could be greater or less support.

B. In education, there could be changes in distribution.

C. Changes in Federal support could take the form of fluctuations in funds or modifications of the Federal role.

D. Broad institutional support could be formula-based or by negotiation.

E. To speak of options implies a measure of control by the medical schools acting collectively. This was my intention.

V. There are many possible approaches implicit in ongoing studies on--

A. Training grants,

B. Health options,

C. The medical schools themselves, conducted by AAMC:

1. Enrollment increases (Howard commission).

2. Research policy (Welk commission).

3. Cost study.

4. Models (Wilson).

5. Others.

VI. Conclusions.

TAB 5

BIOMEDICAL RESEARCH IN THE U.S.A., 1970*

Robert Q. Marston, M.D.

The subject that I am here to discuss today--biomedical research in the United States--while essentially domestic, may also be of interest to those in other countries. Perhaps it is even well to recall that it was Disraeli, not Gladstone, who provided us with the oft-quoted justification for social investment in health: "The health of the people is really the foundation upon which all their happiness and all their powers as a State depend."

There are three reasons that a special look at U.S. medical research at this time may be helpful. First, the question of our national intentions in this area; second, the current ferment in the whole health field in the States; and third, the obvious internationality of scientific discovery. The latter point requires no elaboration for this group, but I would speak briefly to the first two before proceeding to outline what we do and how at the National Institutes of Health and then to enumerate a few of the areas in which we see substantive progress.

There is a myth that the rapid growth of biomedical research in the United States between the mid-fifties and early sixties was primarily a result of the accident of strong congressional personalities--Senator

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*Prepared for presentation before the Medical Research Council, London, England, October 22, 1970.

**Director, National Institutes of Health, U.S. Department of Health, Education, and Welfare.

Lister Hill and Representative John Fogarty--plus strong lobbying efforts for research on categorical diseases. Undoubtedly those leaders were very important, but the circumstances were such that they could lead. Remember that Erasmus Darwin's ideas on evolution were only a topic of academic discussion, while those of his grandson Charles, admittedly more mechanistic, received support outside of academia; the world was then more ready for them.

After World War II the people of the United States and elsewhere had seen the fruits of scientific inquiry not only in devastating weaponry but also in the technological development of a remarkably beneficent agent, penicillin. They were ready to support science for health's sake. And this they did with the leadership of their representatives in the Congress--especially Fogarty and Hill--with increasing support for research on diseases which they identified as especially serious. Thus the development of the categorical Institutes at NIH was fostered. Subsequent developments in the control of polio, measles, and more recently the rubella vaccine, and other advances like the remarkable reduction in debility due to hypertensive cardiovascular disease, have--I believe--sustained their enthusiasm for research in the biomedical sciences.

There is abundant evidence of the general support that medical research commanded during the years of rapid growth. It may be found, for example, in the ten special studies of NIH reported by outside agencies since 1960. And there is the evidence of the step-by-step development of a portfolio of support mechanisms rather uniquely suited for specific national conditions and opportunities. I will speak later, however, of the degree to which these conditions in the health field are currently changing.

A recent memorandum from NIH to Secretary Richardson has this to say about the development of biomedical capability in the United States:

> For reasons only dimly understood, the last few years have witnessed a rapid growth in public ennui on the value of biomedical research and a growing disenchantment with it, even among medical and graduate students, whose focus of interest has shifted to more immediate and relevant problems. At the same time, a whole new series of concerns has emerged within the Nation, both in relation to health and to other areas. The organization and delivery of health services have moved to center stage in health areas, and the environment, urban decay, welfare, urban and inter-urban transportation, etc., have all emerged as vigorous claimants for a larger absolute and relative share of national and particularly Federal resources.
>
> The NIH has been and remains profoundly convinced that a vigorous biomedical research effort is of critical importance to the Nation. In our concern for delivery of health care, it should be remembered that progress to the extent that it has occurred in this aspect of human history can be viewed as equipping the priest with increasingly effective tools to supplement whatever beneficence flowed from "the laying on of hands." There are still enormous domains of disease in which health care has little to offer of real value and in which the most elegantly designed and comprehensive "delivery system" has naught to deliver but compassion. Without depreciating the importance of other problems which confront our society, it is important to reaffirm the conviction of this Agency that life and good health are obviously very close to "top" priority for most individuals in our society.

I speak here at length and with passion about *research* for three reasons.

- National research capability is the most difficult to build of all capabilities in the health area. It depends on creative people--rare commodities--and on securing fiscal resources from public bodies on long-term promissory notes for pursuit of arcane activities.

- Research has been magnificently contributory, and through the most applicable criterion thereof, retrospective evaluation, supremely relevant. But in the ebb and flow of public favor, it is going out of style at this time.

- Public attention has focused primarily on the fiscal constraints for research. The scientific and medical academic communities are at least as concerned by their perception of questions of durability of basic commitments and precipitous and capricious decisions.

- Unless positive action is taken soon by Government to assure the scientific community of the sincerity and depth of the Federal commitment, the whole enterprise could collapse badly. Research is truly at the crossroads.

Biomedical capability in the post-war United States was developed to meet domestic needs in health through direct Government intervention during a period when Federal involvement in services and education was very limited. It is quite clear, however, that medical research shares with other selected areas of science and technology the national intention to remain at the very forefront of competence. The question that was raised both abroad and domestically as the growth of research support slowed in the mid-sixties and then stopped toward the end of the decade is whether the national intention has changed, both in terms of the importance of medical research to domestic health problems and the determination to maintain a position of international leadership in biomedical science.

Let me put the issue more bluntly. The general view in the United States and abroad is that both words and action seem to indicate a major reduction since about 1967 in the national priorities in these areas. A more accurate interpretation, both of the late Johnson years and the

early Nixon years, is that other priorities have emerged in the Federal domain to compete for limited resources.

I turn now to my second area--the ferment in the whole health field in the States. Here I can speak as one who lived in your country for a year preceding the implementation in July 1948 of your national health system and for a year following that event. I do not think that the United States will follow your model, but we are involved at present in the type of major national debate that goes far beyond the health professions and can only be resolved ultimately by the ballot box in our form of government. Few, I think, would question the probability of major changes both in the organization and delivery of health services and in the way decisions in this area are made. It is much easier at this time to predict the former changes than the latter. The implications are profound for biomedical education and research, if only because we have chosen to defend to a greater degree than you the conduct of biomedical research by the nation's medical centers.

Against these two general spheres of debate--first, the national intention regarding the support of science generally and biomedical research specifically and, second, the ferment in the whole health area--let me present the situation in the States at this time by sketching briefly the operational system as it works day by day, with its current budgetary implications, and then some examples of substantive scientific interest.

About five years ago, Dr. Shannon reported to you informally about the organization of American biomedical science. The system remains essentially as he described it, but the conditions under which such a system can in fact be maintained are better defined than was possible then.

You will recall the prominent role of NIH in biomedical research generally, and in the support of academic science, to the extent that the Federal Government is involved.

NIH continues to support about a third of the nation's biomedical research and development. In fiscal year 1970 the total national investment was an estimated $2.7 billion, of which the Government funded 62 percent and industry 28. NIH provided 53 percent of the total Federal contribution and 33 percent of all Federal funds to academic science, defined as R & D, training, facilities and other resources.

Shifting from the source of funds to the performers of research, academic institutions remain paramount, conducting 35 percent of all biomedical R & D. Industry conducts a third and the Government about a sixth.

Medical schools continue to depend heavily on NIH for the support of science. Altogether the schools report that Federal funds account for upward of half their total expenditures and about 80 percent of their expenditures for sponsored research.

Finally, I would remind you that NIH funds for the support of research and research resources are allocated by a variety of mechanisms. Let me dwell for a moment on the one that accounts for about half of our budget--that is, the regular research grants. To some extent this means of allocation has helped us achieve that independence of program judgment from political expediency spoken to so strongly in Sir Harold Himsworth's book, _The Development and Organization of Scientific Knowledge_.* Here

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*Heinemann, London: 1970, p. 102.

is an excerpt from a memorandum by Christopher Addison on the Ministry of Health Bill of 1919, referring to the work of the Medical Research Council:

> 'A progressive Ministry of Health must necessarily become committed from time to time to particular systems of health administration. . . . One does not wish to attach too much importance to the possibility that a particular Minister may hold strong personal views on particular questions of medical science or its application in practice; but even apart from special difficulties of this kind, which cannot be left out of account, a keen and energetic Minister will quite properly do his best to maintain the administrative policy which he finds existing in this Department, or imposes on his Department during his term of office. He would, therefore, be constantly temped to endeavor in various ways to secure that the conclusions reached by organized research under any scientific body, such as the Medical Research Committee, which was substantially under his control, should not suggest that his administrative policy might require alteration. . . . It is essential that such a situations should not be allowed to arise, for it is the first object of scientific research of all kinds to make new discoveries, and these discoveries are bound to correct the conclusions based upon the knowledge that was previously available and, therefore, in the long run to make it right to alter administrative policy. . . . This can only be secured by making the connexion between the administrative Departments concerned, for example, with medicine and public health, and the research bodies whose work touches on the same subjects, as elastic as possible, and by refraining from putting scientific bodies in any way under the direct control of Ministers responsible for the administration of health matters.'

Passing now to substantive aspects of biomedical science, I should like to say a few words about our general view at NIH on the search for new basic knowledge within the framework of a categorical disease approach.

Though parochial, the subject will interest you inasmuch as the pursuit of knowledge is an international calling and the whole world awaits the success of inquiry into the nature of life, health and disease.

Parenthetically, I should like to comment that the subjects of recent work at the National Institute for Medical Research, as described in materials that Dr. Gray has so thoughtfully provided, bear a remarkable resemblance to those conducted at Bethesda and under our grants. It would appear that our respective investigators see eye to eye on the importance of studying, by divers approaches, the intermediary metabolism and synthesis of proteins, the nature of adaptive systems in bacteria, the mode of action of antibiotics, the biosynthesis of cholesterol, and numerous other problems. As I discuss substantive matters (but at the level of policy) you will recall that the areas of greatest interest at NIH run closely parallel to those at NIMR.

Much progress that civilization has witnessed in our lifetime has derived from the application of general laws of the physical universe, developed and tested by brilliant, creative and intuitive intellects. In contrast, however, biomedical science is still "a scanty patchwork of basic principles that are truly known"--as Paul Weiss, Professor Emeritus of the Rockefeller Institute, describes the current state of knowledge.

I have had some discussions with NIH staff on the prospects of biomedical research for attaining a consistent and comprehensive understanding of the phenomena of life. Reviewing the advances of the past in the unraveling of the genetic code, in protein synthesis, in virology, in cell biology and other fields, one can speculate on how long it will be before we can make broad generalizations about the nature of living things.

Perhaps we are in a period when we can engage in science fiction, which was the specialty of underpaid and underemployed physicists of the depression years. But ours would have to be more limited and speculative, for we have so much less in the way of generalities to draw on.

It would probably be better to wait for major achievements in the pursuit of new goals in biological research. Weiss describes these goals aptly as the understanding of organization and specificity. We can safely wager that some of this understanding will come, for example, from studies on the control of transcription as it relates to differentiation of cells and from developing knowledge of protein structure and its relation to biological activity.

We have to understand membrane structure and function as affecting the transport of substances into and out of cells. As a corollary, such knowledge of membranes is vital to an understanding of cellular immunity--again specificity. We have to understand the molecular mechanism for the distribution and action of hormones, drugs, and toxicants as they relate to receptors and effectors, and the relationship of their structure to their activity. I am becoming more specific and straying from the general goal when I mention such things as the mapping of human chromosomes and the study of mechanisms controlling cell division. These and numerous other fields of inquiry--antiviral substances, viral oncology, and the immune mechanism, to name only a few--may help us to arrive eventually at generalizations as prolific of results as those in the physical sciences.

In the meantime, however, those of us in the biosciences who are concerned particularly with human health must content ourselves with attacking immediate problems through whatever strategies we can derive

from the explorations toward general goals, which we must also support. Thus there is an intellectual rationale for the categorization of biomedical research into areas that are of interest to us and to our benefactors as imperative problems. If we have broad enough support in these areas, and ensure the pursuit of basic science, we can hope to achieve in the long run both the specific and the general goals.

Returning now to the broader theme of national health goals, one must acknowledge that the need for concerted efforts to close the gaps in our national health system is clear and indisputable. No one doubts that the most serious of our problems concern the organization and delivery of comprehensive service--preventive, curative, restorative. But even if we had achieved an ideal system for delivering health services, we would still face continued gaps between expectation and realization. And the most important ones would be manpower and knowledge.

We must of course increase the availability of adequately trained health personnel. In doing so, we face an age-old dilemma: Shall we hold out for the best scientific and technical competence, or settle for provision of immediately available, personal, and compassionate care? But human needs cannot be met by the automated lab and the computer, any more than they can by the incompetent though compassionate well-wisher.

Even with the most carefully contrived system and the best of health education, the level of medical care in the future, as in the past, will be largely determined by the state of medical knowledge. And it seems likely that public expectations will in general continue to exceed what can be done through medical science.

One reason that expectations concerning medical science tend to exceed reality is the confusion between complex engineering feats and the discovery of basic knowledge. Scientists today are probing the deepest mysteries of basic life processes. And the implications of their work have profound meaning for all of society. Because such research deals with the unknown, the emphasis must be on creativity, not programming; on science, not engineering; on the important, not the immediate.

On balance, I should say that the climate for the support of biomedical research in the United States is a little better today than it was a year or two ago, and that this improvement is reflected in the 1971 budget that awaits final congressional action. And efforts are continuing, inside and outside of government , to find a reasonable basis for funding medical science and sustaining the institutions that house it.

"Knowledge and Wisdom shall be the stability of thy time." So reads an inscription on one of our buildings. Viewed in the short-term, this observation may seem less than valid today. But this is because investment in the future rather than concentration on current needs has always required qualities difficult to discern--informed leadership, foresight, and dedication. These qualities are not lacking in the research community, and in the end they will shape the contribution that science and medicine will make to all mankind.

TAB 6

THE OUTLOOK FOR BIOMEDICAL RESEARCH*

ROBERT Q. MARSTON, M.D.**

This kind of a review, combined with a forward look in our respective fields of science, could not be more timely. The start of a new decade marks a quarter-century of experience following Dr. Vannevar Bush's remarkable and precedent-setting report Science, the Endless Frontier. We are also in a period of nationwide ferment about the uses, the meaning, and the promise of science in our society.

The basic question asked of all science by society is the same--how can science and technology be applied most effectively to solve the problems of man? In the health sciences, however, there is a special urgency today. The general perception of a "crisis in health care," a "crisis in health manpwer," and a "crisis in medical schools" constitutes a significant consideration in the outlook for biomedical research in 1970 for an agency whose sole reason for being is the improvement of the health of the American people.

*Presented at a symposium on "Science and the Federal Government, 1970," at the Chicago meeting of the American Association for the Advancement of Science, December 30, 1970.
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A Quarter Century of Biomedical Research in Retrospect

President Roosevelt had requested Dr. Bush's recommendation along just these lines 25 years ago. "With particular reference to the war of science against disease," the President asked, "what can be done now to organize a program for continuing in the future the work which has been done in medicine and related sciences?"

Another of the President's questions is highly relevant: "Can an effective program be proposed for discovering and developing scientific talent in American youth so that the continuing future of scientific research in this country may be assured. . .?"

Dr. Bush's principal recommendation concerning medical research is as follows:

> It is clear that if we are to maintain the progress in medicine which has marked the last 25 years, the Government should extend financial support to basic medical research in the medical schools and in the universities, through grants both for research and for fellowships.

The growth of both Federal and national expenditures for research and development was gradual until fiscal 1957, when a sudden expansion brought NIH research support to $125 million. Then Federal support began to accelerate as Sputniks I and II gave a spurt to all U.S. science.

By 1967--ten years later--Federal support of biomedical research was twice the nonfederal, or about $1.5 billion.

1967 also marked the cessation of rapid growth in Federal medical R & D. The subsequent NIH budgets represent a plateau in funding, or a decline, estimated as high as 25-30 percent, in terms of program support. This has not been compensated by additional support from the private sector. The revised 1971 President's budget, however, would check this downward drift, maintaining present program levels and allowing for inflation. It also calls for substantial increases in selected areas such as reproductive biology, environmental health science, cancer heart and dental research.

Another of Dr. Bush's recommendations called for grants for institutional support. NIH institutional research support has taken four discrete forms:

- The general research support grant--a formula grant based primarily on the amount of research and institution sponsors.
- Research Training Grants, which permit the recipient a wide degree of latitude in training medical scientists and, in areas of special need, clinical specialists, including the provision of individual stipends.
- Construction of research facilities.

- Provision of special resources for conducting research, such as animal-production facilities and computer centers.

The spirit of the various 1945 recommendations has been embodied in NIH programs. In fact, most of the proposals of the report have been carried out with a success exceeding the fondest dreams of those days.

What then can be said of the advance in providing increased knowledge for the improvement of human health which was the reason for the whole biomedical effort? Quickly and somewhat simplistically, we can answer:

- Dramatic success in the control, prevention, and cure of acute biological events and diseases, such as the whole range of infectious diseases;

- Progress in surgery and related fields;

- Short-term control of physiological and biochemical processes at a very sophisticated level;

- Significant but much more modest success in chronic diseases, and in problems of human development and behavior;

- Provision of a sound scientific capability base for the future.

At the very least the accomplishments of biomedical science in this brief time have changed our whole concept of health and disease, have revolutionized the practice and teaching of medicine, and have raised the level of expectations of

the people to a very high point indeed. Yet the dangers of over-promise are so real that a candid view of the future requires some caution.

The Biomedical science Frontier today

Many of the changes that civilization has witnessed in our lifetime have derived from the application of general laws of the physical sciences discovered, applied, and tested by brilliant and creative intellects. In contrast, biomedical science is still only "a scanty patchwork of basic principles that are truly known"--in the words of Paul Weiss, Professor Emeritus of the Rockefeller Institute.

What are today's prospects of biomedical research for attaining a consistent and comprehensive understanding of the phenomena of life? Reviewing the advances of the past in the unraveling of the genetic code, in protein synthesis, in virology, in cell biology and other fields, one can speculate on how long it will be before we can make broad generalizations about the nature of living things.

Such generalizations, however, will almost surely require major achievements in the pursuit of long-sought goals in biological research. Weiss describes these goals aptly as "specificity and the understanding of organization."

We can safely wager that some of this understanding will come, for example, from studies on the control of transcription as it relates to differentiation of cells and from developing knowledge of protein structure and its relation to biological activity.

We need to understand membrane structure and function as they affect the transport of substances into and out of cells. As a corollary, such knowledge of membranes is vital to an understanding of cellular immunity. We need to understand the molecular mechanism for the distribution and action of hormones, drugs and toxicants as they relate to receptors and effectors, and the relationship of their structure to their activity. More specifically, we might mention such things as the mapping of human chromosomes and the study of mechanisms controlling cell division. These and numerous other fields of inquiry--antiviral substances, viral oncology, and the immune mechanism, to name only a few--may help us to arrive eventually at generalizations as fruitful of results as general theories have been in the physical sciences.

In the biosciences, however, we may have to continue for many years to advance problem by problem and step by step, only rarely reqarded by a discovery as noteworthy as penicillin for infectious diseases or the decoding of DNA as a basis for progress in genetics. I would assert that, in either case, the biomedical frontier today is immensely more promising than 25 years ago. The prospect of using these sciences to improve further the health of mankind is bright indeed.

Basic Questions Reexamined

Vannevar Bush's report focused not only on opportunities for science but on the national role in fostering science for social purposes. Recall that his charge was, "With particular reference to the world of science against disease--what can be done now to organize a program?" And secondly, "Can an effective program be proposed for discovering and developing scientific talent in American Yourth." These questions have a familiar ring today. Despite the fact that programs have grown rapidly and scientific accomplishment has been dramatic, questions continue to arise regarding public policy in the support of biomedical research and the nature of the central organization of science.

Only a few weeks ago, the National Academy of Sciences issued a report on the life sciences, and called for a clearer public policy in this field.

Obviously NIH is deeply involved in these policy questions. It has initiated or cooperated in ten in-depth studies of various aspects of its role and function. The Wooldridge Committee report in 1965 is perhaps the best-known example.

The policy issues have been sharpened with the passage of years and more recently by the sense of impending change in national health programs. An examination of some of these key issues should allow us to establish at least the perimeters to the outlook for biomedical science in the immediate future. Any serious consideration of biomedical research policy must examine three related areas: the impact of such policies on health generally; their impact on the universes of science; and their impact on the institutions of higher learning, especially the medical schools. It has become clear that a number of issues which were relatively unimportant when budgets were rising may become quite acute under conditions of stable funding.

Thus, I would refer now to three issues raised in Bush's report which are still incompletely resolved:

1. What is the nature of the decision-making process for a biomedical research program for the future?

2. What are the best mechanisms of support?

3. What should be the relationship with medical and other health educational schools?

First Issue: What is the nature of the decision-making process, and how are resources allocated and distributed through an organization like NIH?

Sir Harold Himsworth, in his book on the development and organization of scientific knowledge, points out that "it would be idle to pretend that . . . any country has yet solved the problems posed by the emergence of science as a recognized social force." On the one hand, national science policy must depend heavily on the best judgment and the opportunities within the scientific community; yet in the broadest terms, the decisions on the needs of modern society are the proper concern of elected officials.

Scientific administrators naturally tend to place primary emphasis on assessments of scientific opportunity and to maximize the limits within which decisions should

be left to their "professional judgment." On the other hand, the Executive and Legislative Branches tend in supporting science to exercise a degree of control which extends to specific direction as to how various amounts shall be spent.

Historically, Congress has engaged in an appreciable amount of "earmarking." Recently, the Executive Branch, beginning in President Johnson's administration, has been moving more and more in the direction of specifying amounts for "new research initiatives."

The question of the programming and administration of a balanced scientific program is certainly one of high policy importance. For example, the policy issue stands out clearly when we consider the relationship of the support of targeted research to that of fundamental science.

It is idle, however, to attempt to deal with the question by drawing a sharp distinction between policy and science, consigning judgments on the former to the Executive and Congress and reserving those on the latter to the operating agency or to the so-called scientific community.

The line between purely scientific and technical judgment and broad policy is desirably an indistinct one. Operating agencies must be concerned with policy. They are responsible for recommending policy to higher echelons based on their program expertise and experience. And higher echelons obviously have a right to raise questions concerning the management of programs at the operating level, whether scientific or otherwise.

Himsworth has posed the question "what does a modern society as expressed by its government now need from its scientists over and above their own personal contributions to research?" He suggests three things: to promote research in various scientific fields; to develop effective arrangements by which government is kept informed of scientific developments and by which problems that depend on scientific knowledge for their solution can be given informed assessment; and advice on the deployment of resources between the different provinces of scientific endeavor. He then points out that "the essence of Government is choice," and that the scientific community must participate fully in the process of decision.

Twenty-five years ago the problem in this community was to develop a national capability of excellence and effectiveness. That ambitious goal has been achieved beyond, as I said, our fondest dreams, so that today:--

- The biomedical sciences seem uniquely ripe for vigorous exploration;
- We as a nation seem to be about to undergo major changes in our health delivery systems;
- The question is raised with increasing urgency, How do we arrive at decisions in the use of this biomedical research capability?

One of the key issues is how best to apply the great potential of dedicated scientists and resources in the medical field to brave national health problems. I believe that the time has arrived for all of us, in government and out, to reexamine this problem in all its ramifications, seeking decisions in the open with opportunity for all to contribute.

Second Issue: What are the best mechanisms of support?

I recently met with the chairmen of all the NIH study sections. Without exception, they expressed concern that we are moving away from the investment in the individual scientist to an emphasis on targeted or directed research.

Yet the Committee of Consultants on Cancer has recently recommended a large crash-type program to cure cancer. At the same time, many organizations are seeking special institutes to focus attention and resources in such areas as gastroenterology, kidney disease, lung disease, etc.

The question is not whether targeted or directed research should be emphasized, but how great that emphasis should be. Are the decisions wise? How much targeting can be done without fundamental harm to an effective system of overall support for biomedical research in this country? Do decisions on new initiatives reflect a careful balancing of policy and political goals, with judgments of scientific opportunity? These questions cannot be answered absolutely, and the judgments with respect to them will depend on the vantage point of the judger.

I believe we should maintain a position of flexible diversity. We should not tie ourselves to one course of action.

To make this possible, we need a portfolio of mechanisms for supporting science in this country. We should maintain as the backbone of this portfolio our regular research grants, now constituting somewhat more than half of the total expenditures of NIH. They represent the clearest and most

effective mechanism to focus our resources on the most creative scientists with the best ideas. They constitute a powerful monitoring and evaluative device. These grants are distributed after successive review by two nonfederal groups--the study sections and the councils. In addition, however, training grants, fellowships, institutional support mechanisms, center grants, contract funds, and intramural programs all have an appropriate place in our total national endeavor.

Third Issue: What should be the relationship of NIH to institutions, especially medical schools?

The basic mission of the National Institutes of Health is to improve the health of the American people through research, to assist in the education of health personnel, and to support biomedical communications. It is clear that the biomedical research activities of the nation are dependent on the colleges and universities of the land. Thus from the beginning, NIH has had close ties with the academic community, first through individual project grants and later through institutionally oriented grants. In recent years a new dimension was added to our relationship with health professional schools through our health manpower

responsibilities. This has come about at a time when financial crises are emerging in many of our nation's medical schools. The Carnegie Commission on Higher Education predicts similar problems in institutions of higher learning generally.

These events and the relationship of the Federal Government to the health educational institutions of the country, particularly to medical, dental and osteopathic schools, have led us to review carefully the various positions taken in the Carnegie Commission's report "Higher Education and the Nation's Health." Among the key concerns here will be a clearer definition of the various causes of financial problems; the appropriate degree of Federal responsibility for institutional support; and the question of whether the public purpose will best be served by a "first dollar" approach which I favor or a "last dollar" approach as the dominant mechanism of support, or by a combination of the two.

<u>The Final Issue I wish to pose is a question of priorities in the general allocation of resources</u>.

What is the place of biomedical research vis-à-vis the organization and delivery of health care and other national obligations? This issue is sharpened greatly by the contrast of rapidly escalating health costs at a time of severe budget

constraints. NIH is appropriately a part of the Department of Health, Education, and Welfare. Thus, the trade-off possibilities in budget development within the Department tend to be between welfare, education and the other components of health, although both the Office of Science and Technology and the Office of Management and Budget, in arriving at their recommendations, array the budget along functional rather than organizational lines. Inevitably research has to compete with other national needs, such as education and training of health personnel, the organization and delivery of care, and even medicare and medicaid. Although we can deplore dollar trade-offs, they probably are an inescapable part of life.

Of greater importance as this country seeks to provide a more rational health system for its people is the likelihood that biomedical research will be challenged as a less effective means of achieving that goal, at least in the short-run, when compared with other means. At a time of major national change in the health field, it is inevitable that the question of the relevance of research will be raised. Answers must be given in terms of national need, not

defense of the status quo. A convincing case can be made that health care in the future, as in the past, will depend primarily on the knowledge base from which it is practiced.

History provides not only striking evidence of the high social yield growing out of biomedical science, but also of how, in times of greatest stress, nations have recognized the importance of basic research. Lady Florey, with whose husband, Howard Florey, I worked almost 25 years ago, visited us recently, and we discussed the wisdom of war-time England's allowing the continuation of studies of natural antagonisms which led to a reexamination of Flemming's mold and the production of penicillin. This activity was continued in the face of possible invasion. Indeed several members of the laboratory had the mold sewn in the lining of their clothes, so that if England were invaded, those who escaped would still be able to continue the work.

In conclusion, let me say that I have talked about what Bush talked about--that is, the creation of a national effort in biomedical research--and have spent less time on the nature of research opportunities before a group as scientifically knowledgeable and sophisticated as this.

I will end by pointing out a special problem in the interpretation of the nature of scientific evidence in the future.

Florey's 100 percent fatality of untreated mice and 100 percent survival with penicillin required little explanation. The applicability of the results of much of today's research is not as clearcut. There are benefit-risk ratios inherent in many modern discoveries which must be evaluated. I need only mention the antidiabetic drugs and the oral contraceptives to make the point. The character of this issue suggests that the biomedical sciences of the future will offer not only the challenges of probing the basic life processes which I mentioned earlier, but will test severely our ability to make sound judgments in applying the results. The use of the results from the application of scientific experiments must increasingly be weighed against social, economic, political and behavioral beliefs and desires in the population. For this reason alone, the biomedical science frontier is more challenging and more demanding than it was 25 years ago.

I believe the scientific community can help the American people recapture the spirit and the flavor of Dr. Bush's vesion of an "endless frontier." With public support based on this kind of understanding, our future is bounded only by our own creativity and will.

I would end by quoting three sentences from the Oxford History of America.

> "America was discovered accidentally by a great seaman who was looking for something else; when discovered it was not wanted; and most of the exploration for the next fifty years was done in the hope of getting through or around it. America was named after a man who discovered no part of the New World. History is like that, very chancy."

Since the nature of biomedical research is to probe the unknown, we should not be surprised that predictions about the future are also chancy.

TAB 7

OUTLOOK FOR NIH SUPPORT OF MEDICAL EDUCATION AND RESEARCH

Background Information[1]

Robert Q. Marston, M.D.[2]

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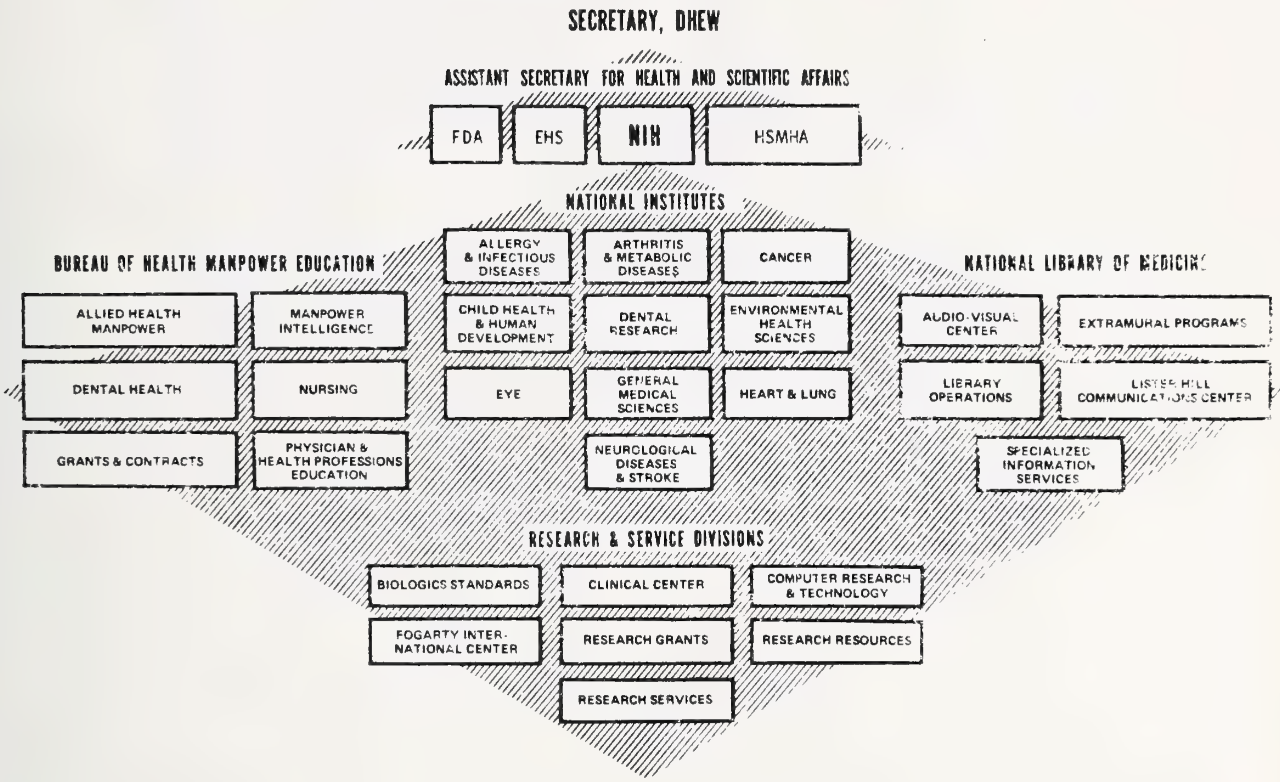
[1]Prepared for meeting of the Assembly of the Association of American Medical Colleges, Chicago, Illinois, February 13, 1971.

[2]Director, National Institutes of Health, U.S. Department of Health, Education and Welfare.

I. ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH



The principal changes over the past year in the operating organization of the health agencies reporting to the Assistant Secretary for Health and Scientific Affairs, DHEW, affected mainly the Environmental Health Service and stemmed primarily from the creation of a new executive agency reporting directly to the President--the Environmental Protection Agency. These changes are as follows:

- Transfer from DHEW to the new agency of air pollution control, water hygiene and solid waste management programs, some functions relating to pesticides, and certain portions of the radiological health program.

- Retention in DHEW of programs to improve the environment of communities, occupational health and safety, the Arctic Health Center, and activities relating to the medical effects of radiation in DHEW (The decision on how these remaining functions will be organized and the disposition of the Environmental Health Service has not been made as of this date).

Within NIH, the major organizational changes are as follows:

- The complete internal reorganization of the Bureau of Health Professions Education and Manpower Training based on program purpose and legislative authority and the renaming of the organization as the Bureau of Health Manpower Education.
- The return of the Division of Research Resources from the Bureau to the research component of NIH and its former status as a separate Division along with the Institutes and other Research Divisions.

The top staff is as follows:

Director	Dr. Robert Q. Marston
Deputy Director	Dr. John F. Sherman
Deputy Director for Science	Dr. Robert W. Berliner
Director, Bureau of Health Manpower Education	Dr. Kenneth M. Endicott
Director, National Library of Medicine	Dr. Martin M. Cummings
Associate Director for Health Manpower	Dr. Leonard D. Fenninger
Associate Director for Program Planning and Evaluation	Dr. Thomas J. Kennedy, Jr.
Associate Director for Administration	Mr. Richard L. Seggel
Associate Director for Communications	Mr. Storm Whaley
Associate Director for Clinical Care Administration	Dr. Thomas C. Chalmers
Associate Director for Extramural Research and Training	Dr. Ronald W. Lamont-Havers
Assistant Director for Collaborative Research	Dr. Leon Jacobs

II. THE CURRENT YEAR (FISCAL YEAR 1971) BUDGET

A. Chronological Development

For the first seven months of this fiscal year, NIH, like other agenices of the DHEW, has been operating under the provisions of a continuing resolution of Congress, which restricted operations to last year's level. However, the fiscal year 1971 appropriations bill, which provides substantial increases in funds for NIH, was passed by Congress and approved by the President on January 11, 1971. Thus, these substantial increases for NIH will be available for use in somewhat less than five months remaining in the current fiscal year. Following is a table which shows the progression of the current year budget (in terms of pluses and minuses) in comparison to last year's budget.

(In thousands)

Activity	F.Y. 1970 Actual	Fiscal Year 1971 Changes Over 1970: President's Budget	Congr. Approp.	1971 Column of 1972 Budget*
Institutes & Research Divisions				
Research grants..............	$592,689	+$15,030	+$79,821	+$70,603
Training grants & fellowships	155,971**	-1,732	+10,730	+3,289
Collab. res.(mostly contracts)	127,088	+43,072	+58,384	+58,828
Intramural research..........	90,302	+9,539	+13,401	+13,551
Other direct operations......	46,471	+2,850	+3,423	+3,823
Subtotal, IRD's............	1,012,521	+68,759	+165,759	+150,094
Bureau of Health Manpower Educ.				
Medical, dental and related health professions.........	301,257**	-2,120	+35,640	+35,640
Nursing......................	50,444	+15,000	+24,500	+24,500
Public health................	17,970	-995	+505	+505
Allied health................	13,380	+6,106	+6,106	+6,106
Prog. dir. & manpower anal...	4,809	+350	+350	+350
Other........................	13,515	-5,738	-5,738	-5,738
Subtotal, BHME.............	401,375	+12,603	+61,363	+61,363
National Library of Medicine...	19,979	+302	+1,302	+1,302
Other..........................	10,058	+7,307	+7,307	+7,307
Total, NIH...............	1,443,933	+88,971	+235,731	+220,066

*Reflects pay increases and decreases for funds held in budgetary reserve.

**Reflects comparative transfer of $23,000,000 for the salary components of research training grants in health professions schools from the Institutes to the Bureau of Health Manpower Education.

B. Explanation

1. The President's 1971 budget, submitted a year ago, provided for the following:

a. An increase over fiscal year 1970 of $68.8 million for research or about 6 percent, reflecting:

(1) Significant increases for cancer ($22.6), family planning and population research ($12.8), early childhood development ($6.5), heart and lung diseases ($13.0), and dental research ($5.9);

(2) A hold-the-line policy on research training grants, pending the outcome of a study of this program; and

(3) A 20 percent decrease ($10.5) in general research support grants.

b. A net increase of $12.6 million for health manpower education, reflecting:

(1) Increases of $19.1 million for project grant support to schools of medicine, dentistry and osteopathy, schools of nursing, and institutions providing allied health training;

(2) A decrease of $4.1 million for student assistance based on the assumption that scholarships and direct loans should go for the most part to students from families with incomes below $10,000 and that students from higher income families should take advantage of the loan guarantee program of the Office of Education;

(3) A decrease of $2.7 million for the elimination of basic improvement (formula) grants to schools of veterinary medicine and reductions in grants for graduate public health training; and

(4) A reduction of $23 million in total obligational authority for construction grants to health professions schools and the anticipation that support of construction of teaching hospitals would be shifted to a loan guarantee method of financing (with Federal subsidy) through the Hill-Burton program.

c. Maintenance of the National Library of Medicine's programs at approximately the previous year's level.

2. Congressional action on the appropriation bill, as compared to the President's budget, provided for the following:

a. A further increase of $97.0 million for research, reflecting:

(1) Increases above the President's budget for cancer ($28.0 million), heart and lung diseases ($21.7 million), stroke in the National Institute of Neurology and Stroke ($8.8 million), and genetics in the National Institute for General Medical Sciences ($10 million); and

(2) Across-the-board "cost of living" increases of $38.5 million designed to bring research activities, including the research training programs and the general research support grant programs, up to the 1970 "program level."

b. Increases for the Bureau of Health Manpower Education of $48.7 million, including:

	(Millions)
Medical, dental and related institutional support (including restoration of $2.7 million for base grant support of schools of veterinary medicine)	$10.7
Nursing institutional support	0.5
Public health training programs	1.5
Medical, dental and related scholarships	0.5
Medical, dental and related student loans	13.0
Nursing student loans	7.5
Construction--of which $1.5 million was for nursing school construction; the remainder for medical, dental and other health professions schools	15.0

c. A $1.0 million increase in the National Library of Medicine, with $0.5 million for the Lister Hill National Center for Biomedical Communications and $0.5 million spread among the other Library programs.

3. <u>The amounts of the fiscal year 1971 appropriations which will be made available</u> through the apportionment process and shown in the 1971 (middle year) column of the President's 1972 budget reflect the following funds held in budgetary reserve:

a. Congressional increases of $7.5 million for research training grants ($0.8 million of the $7.5 million in the Cancer and Heart appropriations will be reprogrammed for purposes other than training); this reflects the hold-the-line policy pending the outcome of the study.

b. $6.5 million of the Congressional increases of $12.9 million for general research support grants ($1.9 million in the Cancer and Heart appropriations to be reprogrammed).

c. $2.25 million from the $10 million Congressional increase for genetics and $2.25 million from the Congressional increase for stroke.

(Note: The use of $15 million Congressional increase for construction grants to medical, dental and other schools will be deferred to fiscal year 1972.)

III. THE PRESIDENT'S 1972 BUDGET

Activity	(In Thousands) 1971 Column Comparable	1972 Estimate	Change
Institutes and Research Divisions			
Research grants.....................	$663,292	$680,516	+$17,224
Training grants and fellowships.....	159,260*	152,679*	-6,581
Collaborative res.(mostly contracts)	185,916	189,814	+3,898
Intramural research.................	103,853	109,009	+5,156
Other direct operations.............	50,294	51,291	+997
Special cancer initiatives..........	--	100,000	+100,000
Subtotal, IRD's..................	1,162,615	1,283,309	+120,694
Bureau of Health Manpower Education			
Medical, dental and related health professions...............	336,897*	421,548*	+84,651
Nursing.............................	74,944	68,018	-6,926
Public health.......................	18,475	18,514	+39
Allied health.......................	19,486	26,494	+7,008
Program direction & manpower anal...	5,159	6,227	+1,068
Other...............................	7,777	7,015	-762
Subtotal, BHME...................	462,738	547,816	+85,078
National Library of Medicine..........	21,281	21,486	+205
Other.................................	17,365	17,803	+438
Total, NIH......................	1,663,999	1,870,414	+206,415

*Reflects a comparative transfer in each year of $23,000,000 from the Institutes to the Bureau of Health Manpower Education for the salary components of research training grants awarded to health professions schools.

Highlights of the 1972 Budget

The President's 1972 budget for NIH provides an overall increase of nearly $206 million, or 12 percent, over fiscal year 1971 and $420.1 million, or 29 percent, over fiscal year 1970.

1. Research: The requested net increase for research over fiscal year 1971 is $121 million, or 10 percent. Compared to fiscal year 1970, which is essentially the level at which NIH has been operating for the first seven months of the current fiscal year, the budget increase for research totals $271 million and amounts to an increase of 27 percent. The major features of the budget for research are:

a. An increase over fiscal year 1971 of $100 million for a special, targeted attack on cancer, which is in addition to a $50 million increase provided in the current year for the research activities of the National Cancer Institute (The details on the $100 million new initiative are to be presented in the President's forthcoming Health message);

b. An increase of $5 million for research in sickle cell anemia to be funded through the National Heart and Lung Institute (Note the NHLI budget in fiscal year 1971 contains an increase of $34 million over fiscal year 1970, mainly for arteriosclerosis and lung research);

c. Increases in other special initiative areas, including over $9 million for family planning research, $5 million for environmental health sciences, and $3 million for dental caries research;

d. Increases of $21.6 million for non-competing continuation research grants ("moral commitments");

e. Decreases totaling $41.7 million in other research areas considered to be of lesser priority--e.g., general research support grants, artificial heart and kidney programs, perinatal studies, drug coronary study, regular research grants and intramural research in non-initiative areas, and fellowships; and

f. A shift of $23 million attributable to the health professions school salary components of the research training grants programs of the several Institutes to the Bureau of Health Manpower Education; the objective is to support the current level of research training pending the outcome of the training study (now scheduled for completion in September 1971) but to do so in such a way as to put more flexible means of control in the hands of the school Deans.

2. Health manpower education: The President's 1972 budget provides a total increase of approximately $85 million over 1971 and $146 million over the 1970 level for health manpower education. The major features are:

a. A net increase over fiscal year 1971 of $84.7 million for support to medical, dental and related health professions schools, reflecting:

(1) A $124.3 million increase for institutional support*
(2) A $3.0 million decrease for direct loans to students
(3) A $37.5 million decrease in grants for school construction
(4) A $1 million increase for dental programs, including fluoridation and training in the use of dental auxiliary personnel

b. A net decrease of $6.9 million for schools of nursing consisting of:

(1) A $7.5 million decrease in direct loans to students
(2) A $1.7 million decrease in construction grants
(3) A $1.0 million increase in training of teachers, supervisors and administrators
(4) A $1.0 million increase for nurse refresher training
(5) A $0.3 million increase for supporting activities

(The fiscal year 1971 budget shows a net increase of $24.5 million for nursing over fiscal year 1970.)

c. A net increase of $7 million in the allied health programs, reflecting:

(1) An increase in institutional support of $0.25 million
(2) An increase of $6.25 million in special projects for experimentation, demonstration, and institutional improvement related to training or retraining of allied health personnel
(3) An increase of $0.5 million for staffing regional offices

3. National Library of Medicine: This appropriation is being maintained at about the 1971 level (which reflects a $1 million increase over 1970).

*This is in addition to the $23 million transfer of research training funds from the Institutes, which is reflected in the budget "base" of the Bureau of Health Manpower Education (i.e., in the 1970 and 1971 columns as well as the 1972 estimate).

IV. FEDERAL BUDGETS FOR MEDICAL R&D, FY 1970-1972
(in millions)

Agency	1970 actual	1971 est. obligations	1972 est. obligations	Increase 1972/71	Percent increase
Total	$1,664	$1,930	$2,078	$148	8
VA	59	62	62	-	0
DoD	125	117	115	-2	-2
AEC	104	105	104	-1	-1
NASA	86	103	78	-25	-24
NSF	28	30	32	2	7
DHEW 1/	1,177	1,321	1,444	123	9
(NIH)	(873)	(1,057)	(1,185)	(128)	(12)
Agriculture	50	55	56	1	2
Environmental Protection Agency	-	85	100	15	18
Other	35	52	87	35	67

1/ For FY 1971 and FY 1972, excludes those research programs transferred to the Environmental Protection Agency, December 1970

Note: Covers support of medical and health-related R&D (projects, resources, and general support) but not training or construction

V. LEGISLATION AND PENDING BILLS AFFECTING NIH'S ORGANIZATION

Enacted Legislation

Family Planning Services and Population Research Act of 1970

S. 2108 (Tydings' bill which received widespread support in the 91st Congress) originally proposed a single new organizational component--the "National Center for Population and Family Planning"--which would encompass all DHEW programs and activities of research and service concerned with the subject areas.

Senator Tydings on February 19, 1970, proposed the establishment of a Family Planning Administration on a par with FDA, NIH, and HSMHA. The Deputy Assistant Secretary for Family Planning and Population would also serve as Director of the new Administration.

The Administration objected to this proposal on several grounds, including (1) the inadvisability of including research and service programs under one "roof"; (2) the fragmentation of NICHD's research programs; and (3) the time lag needed to establish a new, operative agency.

The Administration submitted a counter-proposal (which, in effect, was accepted by the backers of the legislation) which would leave the service and research programs intact in their respective agencies, but which would achieve many of the goals of Senator Tydings' bill by (1) broadening the authority of the Deputy Assistant Secretary for Population Affairs; (2) creating positions for two Special Assistants to the Deputy Assistant Secretary--one concentrating on family planning services and the other concentrating on population research programs; and (3) requiring a five-year plan on DHEW population activities, with special analysis and frequent updating of present and future funding levels, and participation by the Deputy Assistant Secretary in each stage of the budget and program planning process.

The bill, as passed and signed into public law, retained population research activities within the NICHD and consequently no transfer of NIH programs was effected.

Occupational Safety and Health Act of 1970

This broad legislation which was recently signed into law (P.L. 91-596) provides for promulgation and enforcement of standards, largely through the Department of Labor. It also provides, for the first time, a specific statutory basis for DHEW's activities in the field of occupational health and safety.

The Director of the National Institute of Occupational Safety and Health will have authority for the study of specific diseases within the dimensions of the occupational environment, although, in a general sense, responsibility for the study of these diseases is already vested in the various Institutes within the NIH (particularly the NIEHS), as well as in other HEW agencies. For instance, laboratory studies on chronic low-level exposure in the occupational environment are virtually identical with those in the general population. Another example is the problem of pulmonary diseases in the occupational environment (NIOSH) versus the general environment (NIEHS and NHLI).

Pending Bills

Proposed National Cancer Authority

The Chairmen of both the House and Senate Committees having jurisdiction over health legislation introduced bills in December 1970 [S. 4564 (25 co-sponsors), H.R. 19966, and four other House bills] calling for a transfer of employees, contracts, property, and resources from the NCI to the National Cancer Authority. The NCI and National Cancer Advisory Council would "lapse."

On January 26, 1971, Senator Kennedy, new Chairman of the Senate Health Subcommittee, introduced S. 34, the "Conquest of Cancer Act," which would also transfer NCI's functions to a National Cancer Authority. Seven similar bills were introduced in the House.

Proposed National Kidney Disease Act

Forty members of the Senate and 113 members of the House co-sponsored identical bills (S. 2482, H.R. 12425, and others) to amend the PHS Act by adding a new title, "Title X--Education, Research Training, and Demonstrations in the Field of Kidney Disease."

Research related to kidney diseases would be transferred to a new Office of Kidney Diseases, or Kidney-Related Diseases, to be located in the Health Services and Mental Health Administration.

No hearings were held on these bills, and only one similar proposal was introduced during the Second Session. Although the scope of RMP has been expanded to include kidney and other related diseases (P.L. 91-515, October 1970), no research functions are being transferred from the NIH.

However, four new bills similar to those proposed in the last Congress have already been put in the hopper thus far in the 92nd Congress.

Other

The Second Session of the 91st Congress featured a slackening of the brisk pace at which legislators introduced bills to establish new institutes at the NIH. None of the proposals advanced far in the Congressional process. However, the 92nd Congress has already generated a number of bills directly affecting NIH functions.

National Lung Institute (Name of National Heart Institute was changed to National Heart and Lung Institute on November 10, 1969)

H.R. 4822 - Kyros (20 cosponsors), 1/29/69
H.R. 5202 - Kyros (7 cosponsors), 1/29/69
S. 765 - Yarborough, 1/29/69
11 other House bills

National Kidney Institute

H.R. 706 - Whalley, 1/3/69
Reintroduced in the 92nd Congress by Whalley as H.R. 497, 1/25/71

National Institute of Marine Medicine and Pharmacology

S. 1588 - Magnuson (4 cosponsors), 3/20/69
H.R. 1397 - Rogers (21 cosponsors), 9/24/69
2 other House bills
Introduced in the 92nd Congress by Downing as H.R. 549, 1/25/71
[Another bill, H.R. 16536, Jarman, 3/18/70, would place responsibility for marine biomedical research within the NIGMS.]

National Institute of Digestive Diseases and Nutrition

H.R. 8978 - Staggers, 3/13/69
S. 3063 - Yarborough, 10/21/69
H.R. 17210 - Hanna, 4/23/70
Introduced in the 92nd Congress by Kennedy as S. 305, 1/26/71

National Institute for Population Research

H.R. 9109 - Brown (California), 3/18/69

National Institute of Gerontology

H.R. 15158 - Springer, 12/9/69
H.R. 19057 - Jacobs, 9/9/70
S. 4551 - Eagleton, 12/2/70
Reintroduced in the 92nd Congress by Jacobs as H.R. 188, 1/22/71

National Institute of Biomedical Engineering

S. 1111 - Harris, 2/25/69

TAB. 8

Biomedical Research and the Future[1]

By Robert Q. Marston, M.D.[2]

Today we are in a period of nationwide ferment about the uses, the meaning, and the premise of science in our society. All of science is being asked a basic question--how can science and technology be applied most effectively to solve the problems of man? But the question has a special urgency for the health sciences. The general perception of a "crisis in health care," a "crisis in health manpower," and a "crisis in medical schools" constitutes a significant consideration in the outlook for biomedical research in the decade of the '70.'s. And, of course, it has a special relevance for an agency, NIH, whose sole reason for being is the improvement of the health of the American people.

The years since World War II have witnessed a remarkable growth in American science. I would like to trace that growth very briefly, with respect to biomedical science in general and the National Institutes of Health in particular, and then pose some questions that confront the research community today.

Perhaps the single most significant impetus to American science was the publication 25 years ago of Dr. Vannevar Bush's remarkable and precedent-setting report, <u>Science, the Endless Frontier.</u> Dr. Bush's volume set off a chain of developments that are still in motion today. For example, his principal recommendation concerning medical research set the pattern that has been followed with great success for a quarter of a century. It was as follows:

1/ To be presented to 49th General Session of the International Association for Dental Research in Chicago, Illinois on March 20, 1971.

2/ Director, National Institutes of Health, U.S. Department of Health, Education, and Welfare.

> It is clear that if we are to maintain the progress in medicine which has marked the last 25 years, the Government should extend financial support to basic medical research in the medical schools and in the universities, through grants both for research and for fellowships.

The growth of both Federal and national expenditures for research and development was gradual until fiscal 1957, when a sudden expansion brought NIH research support to $125 million. Then, Federal support began to accelerate as Sputniks I and II gave a spurt to all U.S. science.

By 1967--ten years later--Federal support of biomedical research was twice the nonfederal, or about $1.5 billion.

The rapid growth in Federal medical R & D tapered off in the years from 1967 to 1970. There was a plateau in NIH funding, or a decline, estimated as high as 25-30 percent, in terms of program support. This was not compensated by additional support from the private sector. The 1971 budget, however, checked this downward drift by maintaining present program levels and allowing for inflation. It also provided for substantial increases in selected areas such as reproductive biology, environmental health sciences, and cancer, heart and dental research.

Another of Dr. Bush's recommendations called for grants for institutional support. NIH institutional research support has taken four discrete forms:

- The general research support grant--a formula grant based primarily on the amount of research an institution sponsors.
- Research training grants, which permit the recipient a wide degree of latitude in training medical scientists and, in areas of special need, clinical specialists, including the provision of individual stipends.
- Construction of research facilities.

- Provision of special resources for conducting research, such as animal-production facilities and computer centers.

The spirit of the various 1945 recommendations has been embodied in NIH programs. In fact, most of the proposals of the report have been carried out with a success exceeding the fondest dreams of those days.

What then can be said of the advance in providing increased knowledge for the improvement of human health which was the reason for the whole biomedical effort? Quickly and somewhat simplistically, we can answer:

- Dramatic success in the control,prevention, and cure of acute biological events and diseases, such as the whole range of infectious diseases;

- Progress in surgery and related fields;

- Short-term control of physiological and biochemical processes at a very sophisticated level;

- Significant but much more modest success in chronic diseases, and in problems of human development and behavior;

- Provision of a sound scientific capability base for the future.

At the very least the accomplishments of biomedical science in this brief time have changed our whole concept of health and disease, have revolutionized the practice and teaching of medicine, and have raised the level of expectations of the people to a very high point indeed. Yet, the dangers of over-promise are so real that a candid view of the future requires some caution.

<u>The Biomedical Science Frontier today</u>

Many of the changes that civilization has witnessed in our lifetome have derived from the application of general laws of the physical sciences discovered, applied, and tested by brilliant and creative intellects. In contra

biomedical science is still only "a scanty patchwork of basic principles that are truly known"--in the words of Paul Weiss, Professor Emeritus of the Rockefeller Institute.

What are today's prospects of biomedical research for attaining a consistent and comprehensive understanding of the phenomena of life? Reviewing the advances of the past in the unraveling of the genetic code, in protein synthesis, in virology, in cell biology and other fields, one can speculate on how long it will be before we can make broad generalizations about the nature of living things.

Such generalizations, however, will almost surely require major achievements in the pursuit of long-sought goals in biological research. Weiss describes these goals aptly as "specificity and the understanding of organization." We can safely wager that some of this understanding will come, for example, from studies on the control of transcription as it relates to differentiation of cells and from developing knowledge of protein structure and its relation to biological activity.

We need to understand membrane structure and function as they affect the transport of substances into and out of cells. As a corollary, such knowledge of membranes is vital to an understanding of cellular immunity. We need to understand the molecular mechanism for the distribution and action of hormones, drugs, and toxicants as they relate to receptors and effectors, and the relationship of their structure to their activity. More specifically, we might mention such things as the mapping of human chromosomes and the study of mechanisms controlling cell division. These and numerous other fields of inquiry--antiviral substances, viral oncology, and the immune mechanism, to name only a few--may help us to arrive eventually at generalizations as fruitful of results as general theories have been in the physical sciences.

In the biosciences, however, we may have to continue for many years to advance problem by problem and step by step, only rarely rewarded by a discovery as noteworthy as penicillin for infectious diseases or the decoding of DNA as a basis for progress in genetics. I would assert that, in either case, the biomedical frontier today is immensely more promising than 25 years ago. The prospect of using these sciences to improve further the health of mankind is bright indeed.

Basic Questions Reexamined

Vannevar Bush's report focused not only on opportunities for science but on the national role in fostering science for social purposes. His charge was, "With particular reference to the world of science against disease--what can be done now to organize a program?" And secondly, "Can an effective program be proposed for discovering and developing scientific talent in American Youth." These questions have a familiar ring today. Despite the fact that programs have grown rapidly and scientific accomplishment has been dramatic, questions continue to arise regarding public policy in the support of biomedical research and the nature of the central organization of science.

The policy issues have been sharpened with the passage of years and more recently by the sense of impending change in national health programs. An examination of some of these key issues should allow us to establish at least the perimeters to the outlook for biomedical science in the immediate future. Any serious consideration of biomedical research policy must examine three related areas: the impact of such policies on health generally; their impact on the universes of science; and their impact on the institutions of higher learning, especially the medical and dental schools.

Let me focus on three issues which are still unresolved:

1. What is the nature of the decision-making process for a biomedical research program for the future?

2. What are the best mechanisms of support?

3. What should be the relationship with medical and other health educational schools?

First Issue: What is the nature of the decision-making process, and how are resources allocated and distributed through an organization like NIH?

Sir Harold Himsworth, in his book on the development and organization of scientific knowledge, points out that "it would be idle to pretend that . . . any country has yet solved the problems posed by the emergence of science as a recognized social force." On the one hand, national science policy must depend heavily on the best judgment and the opportunities within the scientific community; yet in the broadest terms, the decisions on the needs of modern society are the proper concern of elected officials.

Scientific administrators naturally tend to place primary emphasis on assessments of scientific opportunity and to maximize the limits within which decisions should be left to their "professional judgment." On the other hand, the Executive and Legislative Branches tend in supporting science to exercise a degree of control which extends to specific direction as to how various amounts shall be spent.

Historically, Congress has engaged in an appreciable amount of "earmarkin Recently, the Executive Branch, beginning in President Johnson's administration, has been moving more and more in the direction of specifying amounts for "new research initiatives," such as dental caries and the cancer conquest program.

Some have viewed this increased questioning the substance and direction of scientific research by non-scientists as a call for more emphasis on targeted versus fundamental research, on short term versus long term investment.

I believe on the contrary that these questions have a much more profound basis--that the public cares little how we weave our magic but only that we continue to do it. I believe society is quite as prepared as scientists to accept uncertainty where knowledge is lacking if they are so told. But scientists--you and I--believing increasingly that only the short term--the immediate--has value in America continue to promise unselectively that success is "just around the corner.". The response often is, here's another $1 million, $10 million, or even $100 million to get us to the corner sooner.

Twenty-five years ago the problem in this country was to develop a national capability of excellence and effectiveness. That ambitious goal has been achieved so that today scientists and non-scientists see:

- The biomedical sciences seem uniquely ripe for vigorous exploration;
- We as a nation seem to be about to undergo major changes in our health delivery systems;
- Today the question is raised with increasing urgency. How do we arrive at decisions in the use of this biomedical research capability? How best to apply the great potential of dedicated scientists and resources in the health field to grave national health problems?

Before examining this question further through the examples afforded by the dental caries and cancer conquest program, let me state that I believe we should maintain a position of flexible diversity. We should not tie ourself to one course of action.

To make this possible, we need a portfolio of mechanisms for supporting science in this country. We should maintain as a backbone of this portfolio our regular research grants, now constituting somewhat more than half of the total expenditures of NIH. They represent the clearest and most effective mechanism to focus our resources on the most creative scientists with the best ideas. They constitute a powerful monitoring and evaluative device. These grants are distributed after successive review by two nonfederal groups--the study sections and the councils. In addition, however, training grants, fellowships, institutional support mechanisms, center grants, contract funds, and intramural programs all have an appropriate place in our total national endeavor. Having said that let me turn to two specific areas in which there is a general consensus that new approaches are indicated:

Dental Caries

Science

Infectious nature

- genes
- organism
- CHo
- several promising leads
- Flavick base esp. important

Society

- prevalence
- cost benefit ratio
- not a dread disease

Cancer

Science

- animal tumors by viruses & prevention thereof
- cancer chemo Rx - leukemia

Society

- dread disease
- undignified painful death
- #2 killer

Science base better in caries
Social pressure higher in cancer
Both necessary for decision

Add component in cancer -- Separate Authority. Administration against--

I'm against--academic and scientific community against.

What should be the relationship of NIH to institutions, especially medical and dental schools?

The basic mission of the National Institutes of Health is to improve the health of the American people through research, to assist in the education of health personnel, and to support biomedical communications. It is clear that the biomedical research activities of the nation are dependent on the colleges and universities of the land. Thus, from the beginning, NIH has had close ties with the academic community, first through individual project grants and later through institutionally oriented grants. In recent years a new dimension was added to our relationship with health professional schools through out health manpower responsibilities. This has come about at a time when financial crises are emerging in many of our nation's medical schools. The Carnegie Commission on Higher Education predicts similar problems in institutions of higher learning generally.

The timeliness of renewal of the Health Professions Education Act has allowed us to review in detail the relationship of the Federal Government to the health educational institutions of the country, particularly to medical, dental, and osteopathic schools. Among the key concerns here have been a clearer definition of the various causes of financial problems; the appropriate degree of Federal responsibility for institutional support; the national need for health manpower; and the question of whether the public purpose will best be served by a Federal "first dollar" approach as the dominant mechanism of support, or by a combination of the two.

The Administration's health manpower proposals, as you know, include elements of both approaches but emphasizes the first dollar they provide for capitation grants without strings but tied to graduate programs to encourag

greater output of physicians and dentists; special project grants to support innovative programs and to aid schools in financial distress; Health Manpower Education Initiative Awards to develop new organizational forms such as consortia and area health educational centers; and extension and liberalization of student loan and scholarship programs. The comprehensive package also contai another major proposal to increase the number of physicians and dental assistant and allied health personnel. Other proposals have already been introduced--Staggers--Rogers--debate level of support as well as others.

The Final Issue I wish to pose is a question of priorities in the general allocation of resources.

What is the place of biomedical research vis-a-vis the organization and delivery of health care and other national obligations? This issue is sharpened greatly by the contrast of rapidly escalating health costs at a time of severe budget constraints. Inevitably research has to compete with other national needs, such as education and training of health personnel, the organization and delivery of care, and even Medicare and Medicaid. Although we can deplore dollar trade-offs, they probably are an inescapable part of life.

Of greater importance as this country seeks to provide a more rational health system for its people is the likelihood that biomedical research will be challenged as a less effective means of achieving that goal, at least in the short-run, when compared with other means. At a time of major national change in the health field, it is inevitable that the question of the relevance of research will be raised. Answers must be given in terms of national need, not defense of the status quo. A convincing case can be made that health care in the future, as in the past, will depend primarily on the knowledge base from which it is practiced.

History provides not only striking evidence of the high social yield growing out of biomedical science, but also of how, in time of greatest stress, nations have recognized the importance of basic research. Lady Florey, with whose husband, Howard Florey, I worked almost 25 years ago, visited us recently, and we discussed the wisdom of war-time England's allowing the continuation of studies of natural antagonisms which led to a reexamination of Flemming's mold and the production of penicillin. This activity was continued in the face of possible invasion. Indeed, several members of the laboratory had the mold sewn in the lining of their clothes, so that if England were invaded, those who escaped would still be able to continue the work.

Florey's 100 percent fatality of untreated mice and 100 percent survival with penicillin required little explanation. The applicability of the results of much of today's research is not as clearcut. There are benefit-risk ratios inherent in many modern discoveries which must be evaluated. I need only mention the antidiabetic drugs and the oral contraceptives to make the point. The character of this issue suggests that the biomedical sciences of the future will offer not only the challenges of probing the basic life processes which I mentioned earlier, but will test severely our ability to make sound judgments in applying the results. The use of the results from the application of scientific experiments must increasingly be weighed against social, economic, political and behavioral beliefs and desires in the population. For this reason alone, the biomedical science frontier is more challenging and more demanding than it was 25 years ago.

I believe the scientific community can help the American people recapture the spirit and the flavor of Dr. Bush's vision of an "endless frontier." With

public support based on this kind of understanding, our future is bounded only by our own creativity and will.

I would end by quoting three sentences from the Oxford History of America.

> "America was discovered accidentally by a great seaman who was looking for something else; when discovered it was not wanted; and most of the exploration for the next fifty years was done in the hope of getting through or around it. America was named after a man who discovered no part of the New World. History is like that, very chancy.

Since the nature of biomedical research is to provide the unknown, we should not be surprised that predictions about the future are also chancy.

TAB 9

OUTLOOK FOR NIH SUPPORT OF MEDICAL EDUCATION AND RESEARCH

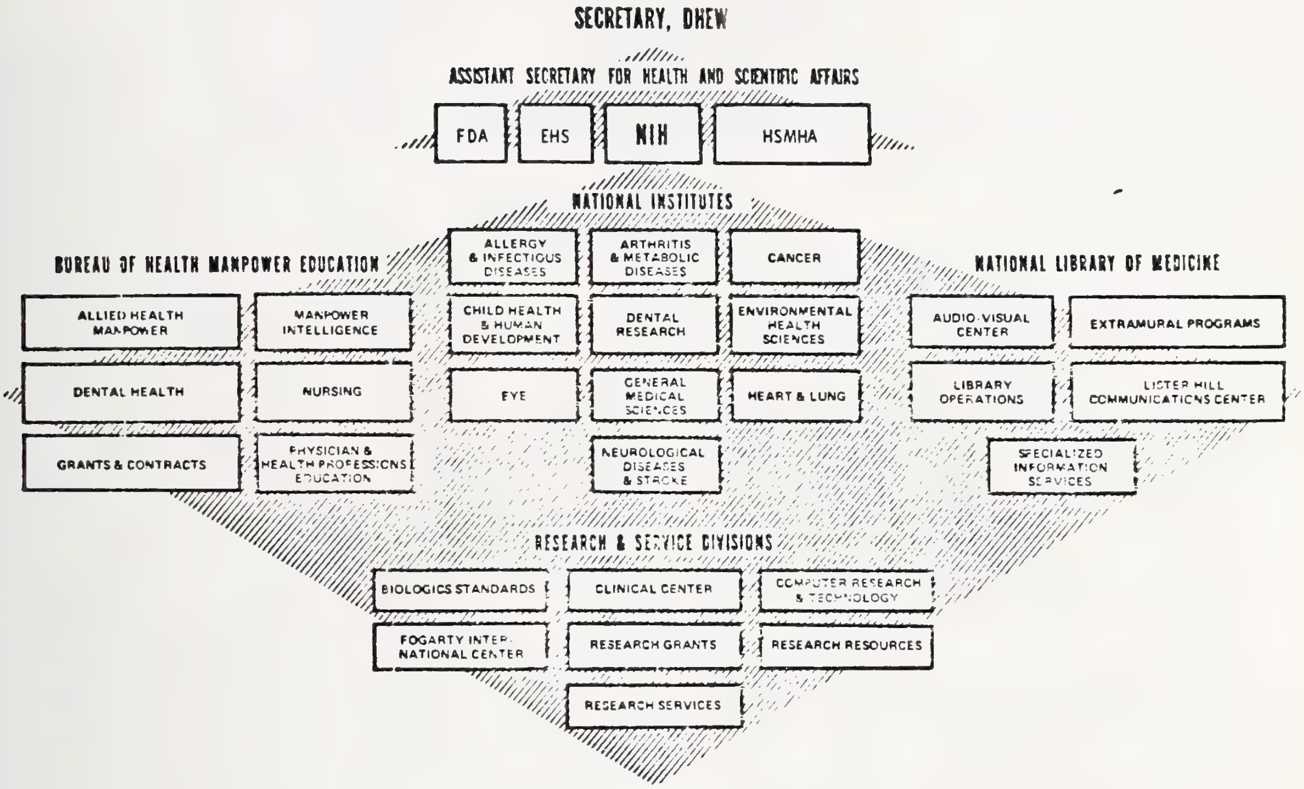
Background Information[1]

Robert Q. Marston, M.D.[2]

[1]Prepared for meeting of the Combined Councils of the Federation of American Societies of Experimental Biology, Chicago, Illinois, April 12, 1971.

[2]Director, National Institutes of Health, U.S. Department of Health, Education and Welfare.

I. ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH



The principal changes over the past year in the operating organization of the health agencies reporting to the Assistant Secretary for Health and Scientific Affairs, DHEW, affected mainly the Environmental Health Service and stemmed primarily from the creation of a new executive agency reporting directly to the President--the Environmental Protection Agency. These changes are as follows:

- Transfer from DHEW to the new agency of air pollution control, water hygiene and solid waste management programs, some functions relating to pesticides, and certain portions of the radiological health program.

- Retention in DHEW of programs to improve the environment of communities, occupational health and safety, the Arctic Health Center, and activities relating to the medical effects of radiation in DHEW (The decision on how these remaining functions will be organized and the disposition of the Environmental Health Service has not been made as of this date).

Within NIH, the major organizational changes are as follows:

- The complete internal reorganization of the Bureau of Health Professions Education and Manpower Training based on program purpose and legislative authority and the renaming of the organization as the Bureau of Health Manpower Education.

- The return of the Division of Research Resources from the Bureau to the research component of NIH and its former status as a separate Division along with the Institutes and other Research Divisions.

The top staff is as follows:

Director	Dr. Robert Q. Marston
Deputy Director	Dr. John F. Sherman
Deputy Director for Science	Dr. Robert W. Berliner
Director, Bureau of Health Manpower Education	Dr. Kenneth M. Endicott
Director, National Library of Medicine	Dr. Martin M. Cummings
Associate Director for Health Manpower	Dr. Leonard D. Fenninger
Associate Director for Program Planning and Evaluation	Dr. Thomas J. Kennedy, Jr.
Associate Director for Administration	Mr. Richard L. Seggel
Associate Director for Communications	Mr. Storm Whaley
Associate Director for Clinical Care Administration	Dr. Thomas C. Chalmers
Associate Director for Extramural Research and Training	Dr. Ronald W. Lamont-Havers
Assistant Director for Collaborative Research	Dr. Leon Jacobs

II. THE CURRENT YEAR (FISCAL YEAR 1971) BUDGET

A. Chronological Development

For the first seven months of this fiscal year, NIH, like other agencies of the DHEW, operated under the provisions of a continuing resolution of Congress, which restricted operations to last year's level. However, the fiscal year 1971 appropriations bill, which provides substantial increases in funds for NIH, was passed by Congress and approved by the President on January 11, 1971. Thus, these substantial increases for NIH are, in a practical sense, available for use in no more than five months during the current fiscal year. Following is a table which shows the progression of the current year budget (in terms of pluses and minuses) in comparison to last year's budget.

(In thousands)

Activity	F.Y. 1970 Actual	Fiscal Year 1971 Changes Over 1970: President's Budget	Congr. Approp.	1971 Column of 1972 Budget*
Institutes & Research Divisions				
Research grants..............	$592,689	+$15,030	+$79,821	+$74,103
Training grants & fellowships	155,971**	-1,732	+10,730	+3,289
Collab. res.(mostly contracts)	127,088	+43,072	+58,384	+55,905
Intramural research..........	90,302	+9,539	+13,401	+15,598
Other direct operations......	46,471	+2,850	+3,423	+4,843
Subtotal, IRD's............	1,012,521	+68,759	+165,759	+153,738
Bureau of Health Manpower Educ.				
Medical, dental and related health professions.........	301,204**	-1,883	+35,877	+22,377
Nursing......................	50,259	+15,249	+24,749	+23,249
Public health................	17,970	-969	+531	+531
Allied health................	13,407	+6,080	+6,080	+6,080
Prog. dir. & manpower anal...	5,020	+252	+252	+252
Other........................	13,515	-10,432	-10,432	-10,432
Subtotal, BHME.............	401,375	+8,297	+57,057	+42,057
National Library of Medicine...	19,979	+302	+1,302	+1,531
Other..........................	10,058	+7,307	+7,307	+7,543
Total, NIH..............	1,443,933	+84,665	+231,425	+204,869

*Reflects pay increases.

**Reflects comparative transfer of $23,000,000 for the salary components of research training grants in health professions schools from the Institutes to the Bureau of Health Manpower Education.

B. Explanation

1. The President's 1971 budget, submitted a year ago, provided for the following:

a. An increase over fiscal year 1970 of $68.8 million for research or about 6 percent, reflecting:

(1) Significant increases for cancer ($22.6), family planning and population research ($12.8), early childhood development ($6.5), heart and lung diseases ($13.0), and dental research ($5.9);

(2) A hold-the-line policy on research training grants, pending the outcome of a study of this program; and

(3) A 20 percent decrease ($10.5) in general research support grants.

b. A net increase of $8.3 million for health manpower education, reflecting:

(1) Increases of $22.2 million for grant support to schools of medicine, dentistry and osteopathy, schools of nursing, and institutions providing allied health training;

(2) A decrease of $3.5 million for student assistance based on the assumption that scholarships and direct loans should go for the most part to students from families with incomes below $10,000 and that students from higher income families should take advantage of the loan guarantee program of the Office of Education; and a decrease of $0.6 million in public health traineeships.

(3) A decrease of $3.1 million for the elimination of basic improvement (formula) grants to schools of veterinary medicine and reductions in grants for graduate public health training; and

(4) A reduction of $23 million in total obligational authority for construction grants to health professions schools and the anticipation that support of construction of teaching hospitals would be shifted to a loan guarantee method of financing (with Federal subsidy) through the Hill-Burton program.

c. Maintenance of the National Library of Medicine's programs at approximately the previous year's level.

2. Congressional action on the appropriation bill, as compared to the President's budget, provided for the following:

a. A further increase of $97.0 million for research, reflecting:

(1) Increases above the President's budget for cancer ($28.0 million), heart and lung diseases ($21.7 million), stroke in the National Institute of Neurology and Stroke ($8.8 million), and genetics in the National Institute for General Medical Sciences ($10 million); and

(2) Across-the-board "cost of living" increases of $38.5 million designed to bring research activities, including the research training programs and the general research support grant programs, up to the 1970 "program level."

b. Increases for the Bureau of Health Manpower Education of $48.8 million, including:

	(Millions)
Medical, dental and related institutional support (including restoration of $2.7 million for base grant support of schools of veterinary medicine)	$10.7
Nursing institutional support	0.5
Public health training programs	1.5
Medical, dental and related scholarships	0.5
Medical, dental and related student loans	13.0
Nursing student loans	7.5
Construction--of which $1.5 million was for nursing school construction; the remainder for medical, dental and other health professions schools	15.0
Division of Dental Health research grants	0.1

c. A $1.0 million increase in the National Library of Medicine, with $0.5 million for the Lister Hill National Center for Biomedical Communications and $0.5 million spread among the other Library programs.

3. The amounts of the fiscal year 1971 appropriations which will be made available through the apportionment process reflects the utilization of the following to cover the deficiency which resulted from increased pay costs. (All funds were used within NIH except $1.9 million transferred to St. Elizabeths Hospital):

a. Congressional increases of $7.5 million for research training grants ($0.8 million of the $7.5 million in the Cancer and Heart appropriations will be reprogrammed for purposes other than pay raise or training); this reflects the hold-the-line policy pending the outcome of the study.

b. $6.5 million of the Congressional increase of $12.9 million for general research support grants ($1.9 million in the Cancer and Heart appropriations to be reprogrammed within these appropriations for uses other than pay increases).

c. $2.25 million from the $10 million Congressional increase for genetics and $2.25 million from the Congressional increase for stroke.

(Note: The use of $15 million Congressional increase for construction grants to medical, dental and other schools will be deferred to fiscal year 1972.)

Activity	(In thousands) 1971 Column Comparable	1972 Estimate	Change
Institutes and Research Divisions			
Research grants	$666,792	$685,341	+$18,549
Training grants and fellowships	159,260*	152,239*	-7,021
Collaborative res.(mostly contracts)	182,993	186,758	+3,765
Intramural research	105,900	113,394	+7,494
Other direct operations	51,314	54,109	+2,795
Special cancer initiatives	....	100,000	+100,000
Subtotal, IRD's	1,166,259	1,291,841	+125,582
Bureau of Health Manpower Education			
Medical, dental and related health professions	323,581	434,045	+110,464
Nursing	73,508	67,000	-6,508
Public health	18,501	18,544	+43
Allied health	19,487	30,654	+11,167
Program direction & manpower anal...	5,272	6,682	+1,410
Other	3,083	4,000	+917
Subtotal, BHME	443,432	560,925	+117,493
National Library of Medicine	21,510	21,981	+471
Other	17,601	18,423	+822
Total, NIH	1,648,802	1,893,170	+244,368

*Reflects a comparative transfer in each year of $23,000,000 from the Institutes to the Bureau of Health Manpower Education for the salary components of research training grants awarded to health professions schools.

Highlights of the 1972 Budget

The President's 1972 budget for NIH provides an overall increase of over $244 million, or 15 percent, over fiscal year 1971 and $449.2 million, or 31 percent, over fiscal year 1970.

1. Research: The requested net increase for research over fiscal year 1971 is $126 million, or 11 percent. Compared to fiscal year 1970, which is essentially the level at which NIH has been operating for the first seven months of the current fiscal year, the budget increase for research totals $279 million and amounts to an increase of 28 percent. The major features of the budget for research are:

a. An increase over fiscal year 1971 of $100 million for a special, targeted attack on cancer, which is in addition to a $50 million increase provided in the current year for the research activities of the National Cancer Institute (the major aspects of the $100 million new initiative were presented in the President's Health message); the present plans provide for the use of $25 million of these funds beginning this fiscal year through the mechanism of advance obligational authority; in this manner, launching of the attack may begin prior to passage of the 1972 appropriation;

b. An increase of $5 million for research in sickle cell anemia to be funded through the National Heart and Lung Institute (Note the NHLI budget in fiscal year 1971 contains an increase of $34 million over fiscal year 1970, mainly for arteriosclerosis and lung research);

c. Increases in other special initiative areas, including over $9 million for family planning research, $5 million for environmental health sciences, and $3 million for dental caries research;

d. Increases of $23 million for non-competing continuation research grants ("moral commitments");

e. Decreases totaling $41.6 million in other research areas considered to be of lesser priority--e.g., general research support grants, artificial heart and kidney programs, perinatal studies, drug coronary study, regular research grants and intramural research in non-initiative areas, and fellowships; and

f. A shift of $23 million attributable to the health professions school salary components of the research training grants programs of the several Institutes to the Bureau of Health Manpower Education; the objective is to support the current level of research training pending the outcome of the training study (now scheduled for completion in September 1971) but to do so in such a way as to put more flexible means of control in the hands of the school Deans.

2. <u>Health manpower education</u>: The President's 1972 budget provides a total increase of approximately $117 million over 1971 and $150 million over the 1970 level for health manpower education. The major features are:

a. A net increase over fiscal year 1971 of $114.5 million for support to medical, dertal and related health professions schools, reflecting:

(1) A $113.0 million increase for institutional support*
(2) A $6.25 million decrease for direct loans to students
(3) A $13.4 million increase for scholarships
(4) A $1 million increase for dental programs, including fluoridation and training in the use of dental auxiliary personnel

b. A net decrease of $6.5 million for schools of nursing consisting of:

(1) A $7.5 million decrease in direct loans to students
(2) A $1.0 million increase in training of teachers, supervisors and administrators
(3) A $1.0 million increase for nurse refresher training
(4) A $0.5 million increase for supporting activities

(The fiscal year 1971 budget shows a net increase of $23.2 million for nursing over fiscal year 1970.)

c. A net increase of $11.2 million in the allied health programs, reflecting:

(1) An increase in institutional support of $0.25 million
(2) An increase of $10.25 million in special projects for experimentation, demonstration, and institutional improvement related to training or retraining of allied health personnel
(3) An increase of $0.5 million for staffing regional offices

d. A $16.0 million decrease in construction assistance to health professions and nursing schools

3. National Library of Medicine: This appropriation is being maintained at about the 1971 level (which reflects a $1 million increase over 1970).

*This is in addition to the $23 million transfer of research training funds from the Institutes, which is reflected in the budget "base" of the Bureau of Health Manpower Education (i.e., in the 1970 and 1971 columns as well as the 1972 estimate).

IV. FEDERAL BUDGETS FOR MEDICAL R&D, FY 1970-1972
(in millions)

Agency	1970 actual	1971 est. obligations	1972 est. obligations	increase 1972/71	Percent increase
Total	$1,664	$1,933	$2,087	$154	8
VA	59	62	62	-	0
DoD	125	117	122	5	4
AEC	104	105	104	-1	-1
NASA	86	103	78	-25	-24
NSF 1/	28	30	32	2	7
DHEW	1,177	1,324	1,438	114	9
(NIH)	(873)	(1,039)	(1,168)	(129)	(12)
Agriculture	50	55	56	1	2
Environmental Protection Agency	-	85	100	15	18
Other	35	52	95	43	83

1/ For FY 1971 and FY 1972, excludes those research programs transferred to the Environmental Protection Agency, December 1970

Note: Covers support of medical and health-related R&D (projects, resources, and general support including PL 480 funding for research) but not training or construction

V. LEGISLATION AND PENDING BILLS AFFECTING NIH'S ORGANIZATION

Health Manpower Legislation

Health Professions Educational Assistance

There are three major proposals so far, offered by the Administration, the Association of American Medical Colleges and the Federation of Schools of the Health Professions, and Representative Paul Rogers (D-Fla.).

The Administration proposal (H.R. 5614, Staggers; H.R. 5767, Nelsen and others; and S. 1183, Javits) would provide for capitation grants of $6,000 per graduate for schools of medicine, osteopathy, and dentistry, with adjustments for student transfers and shortened curricula. It would provide separate authorities for special project grants to schools of medicine, osteopathy, and dentistry; schools of pharmacy, optometry, podiatry, and veterinary medicine; and schools in financial distress. Added are authorities for grants to aid disadvantaged students and to improve area or specialty distribution of manpower and for traineeships in medicine, osteopathy, and dentistry.

A new authority for Health Manpower Education Initiative Awards would permit grants for a variety of purposes, including establishment of area health education centers, training for better health care delivery in the context of the team approach and health maintenance organizations, and the like.

A consolidated construction authority (manpower, medical libraries, and health research) is provided, including authority to make grants (up to 67%), and guarantee loans, and pay up to 3% interest subsidies in the case of private sponsors.

The loan ceiling for health professions students is increased from $1,500 to $5,000 annually under the Higher Education Act of 1965. The bill liberalizes repayment terms and includes Federal repayment of loans to students who practice in health manpower shortage areas or certain specialties in short supply. Also forgiven are loans to students of medicine, osteopathy, dentistry, or nursing who are from low-income or disadvantaged families and who fail to complete their health studies.

The existing scholarship programs for health professions students, which are due to expire at the end of the current fiscal year, are extended for three years. The bill also makes discretionary the present mandatory program of grants for scholarship aid to schools of optometry, podiatry, pharmacy, or veterinary medicine, but continues grants to schools of medicine, osteopathy, and dentistry on the present mandatory footing. It increases maximum health professions scholarships from $2,500 to $3,000 and limits scholarships to exceptionally needy students from low-income or disadvantaged families.

The bill authorizes appropriation of such sums as necessary for the above purposes.

The AAMC proposal (H.R. 4171, Staggers; S. 934, Kennedy) would also provide capitation grants, at the level of $5,000 per student for schools of medicine, osteopathy, and dentistry; $3,500 for optometry, podiatry, and veterinary medicine, and $2,000 for pharmacy. It raises the schools' base grant from $25,000 to $50,000 and authorizes such sums as necessary for formula support. Special project grant authorization for 1972 is $150 million.

The bill would extend existing construction authority for five years, authorizing $300 million for 1972. It would raise the student loan ceiling to $3,500 per year and extend forgiveness provisions to all HPEA professions. It raises the maximum annual amount of scholarships from $2,500 to $3,500 and increases the allotment factor from $2,000 to $3,000 times 10% of enrollment.

A second AAMC proposal (H.R. 4170, Staggers; S. 935, Kennedy) would authorize grants for start-up, construction, and initial operating costs for new or significantly expanded schools of medicine or osteopathy; grants to assist academic health centers in planning and initiating health maintenance organizations; and grants to assist in the establishment of area health education centers.

The Rogers proposal (H.R. 4155) eliminates the base grant to schools and substitutes a $3,500 capitation formula for all enrolled HPEA students. Special project authorization is $105 million for 1972.

Construction authorities (other than health research facilities) are extended for three years, with a 1972 authorization of $325 million. The health research facilities authority is replaced by a new graduate training grant authority for which $10 million is authorized in 1972.

The Rogers student aid proposal is essentially similar to that of the AAMC, except that forgiveness of any educational loan is provided for physicians, dentists, or podiatrists who contract to practice three years in a shortage area.

Nursing

There are two major proposals: the Administration bill (H.R. 5614, above) and Representative Rogers' bill (H.R. 4618). Other bills have been introduced but were not available at this writing.

The Administration bill deletes the authority for construction of nurse training facilities (it is included in the proposed new consolidated construction authority). It would not extend the authority for formula grants but would extend special project grants for three years, adding specific authority to train, or develop training for, new levels or types of nursing or related skills, and to promote full utilization of nursing skills.

It would extend for three years the program of advanced traineeships for professional nurses, and authorize such sums as necessary for such purposes. It would broaden the authority for contracts and grants to identify potential nursing candidates and encourage them to undertake nurse training or retraining.

The Rogers bill (H.R. 4618) would continue the formula grant authority with a grant of $2,000 per full-time enrolled student and would authorize $20 million in special project grants for 1972. It authorizes $40 million in construction grants for 1972.

It would continue the traineeship authority, raise the student loan ceiling from $1,500 to $2,500, and allow forgiveness of up to 100%. The allotment formula for scholarships is increased from $2,000 to $3,000 times enrollment.

Other Pending Bills

Proposed National Cancer Authority

The Chairman of both the House and Senate Committees having jurisdiction over health legislation introduced bills in December 1970 [S. 4564 (25 co-sponsors), H.R. 19966, and four other House bills] calling for a transfer of employees, contracts, property, and resources from the NCI to the National Cancer Authority. The NCI and National Cancer Advisory Council would "lapse."

On January 26, 1971, Senator Kennedy, new Chairman of the Senate Health Subcommittee, introduced S. 34, the "conquest of Cancer Act," which would also transfer NCI's functions to a National Cancer Authority. The bill now has 52 co-sponsors. Twelve similar bills with more than 100 co-sponsors were introduced in the House. Hearings were held on S. 34 on March 9 and 10, 1971.

Proposed National Kidney Disease Act

Forty members of the Senate and 113 members of the House co-sponsored identical bills in the 91st Congress (S. 2482, H.R. 12425, and others) to amend the PHS Act by adding a new title, "Title X--Education, Research Training, and Demonstrations in the Field of Kidney Disease."

No hearings were held on these bills. Although the scope of RMP has been expanded to include kidney and other related diseases (P.L. 91-515, October 1970), no research functions are being transferred from the NIH.

However, six new bills similar to those proposed in the last Congress have already been introduced thus far in the 92nd Congress.

New Institute Proposals

The Second Session of the 91st Congress featured a slackening of the brisk pace at which legislators introduced bills to establish new institutes at the NIH. None of the proposals advanced far in the Congressional process. However, the 92nd Congress has already generated a number of bills directly affecting NIH functions.

National Kidney Institute

H.R. 497 - Whalley, 1/25/71

National Institute of Marine Medicine and Pharmacology

H.R. 547 - Downing, 1/25/71

National Institute of Digestive Diseases and Nutrition

S. 305 - Kennedy, 1/26/71
H.R. 3665 - Staggers, 2/4/71
H.R. 4837 - Hanna, 2/23/71

National Institute of Gerontology

H.R. 188 - Jacobs, 1/22/71
S. 887 - Eagleton, 2/19/71

H.R. 4979 - Jarman, 2/25/71
H.R. 6405 - Thone, 3/18/71

Enacted Legislation

Occupational Safety and Health Act of 1970

This broad legislation which was recently signed into law (P.L. 91-596) provides for promulgation and enforcement of standards, largely through the Department of Labor. It also provides, for the first time, a specific statutory basis for DHEW's activities in the field of occupational health and safety.

The Director of the National Institute of Occupational Safety and Health will have authority for the study of specific diseases within the dimensions of the occupational environment, although, in a general sense, responsibility for the study of these diseases is already vested in the various Institutes within the NIH (particularly the NIEHS), as well as in other HEW agencies. For instance, laboratory studies on chronic low-level exposure in the occupational environment are virtually identical with those in the general population. Another example is the problem of pulmonary diseases in the occupational environment (NIOSH) versus the general environment (NIEHS and NHLI).

TAB 10

#671 Hauser

April 28, 1971

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Statement by Director, National Institutes of Health

on

1972 Appropriation Estimates

Mr. Chairman and Members of the Committee:

I always welcome the opportunity to testify before this Committee about the goals, the plans and the needs of NIH in carrying out its responsibilities for medical research, education in the health professions, and biomedical communication. Today I am particularly pleased to do so because you have before you budget estimates for NIH which I feel I can defend not only with a good conscience but with some enthusiasm. This does not mean, of course, that the budget fulfills all our desires or even that it satisfies every identifiable need. In an activity so broad in scope and so varied in substance as that of NIH, it is inevitable that choices have to be made, that priorities must be weighed, and that some desirable--and readily justifiable--projects must be deferred. But the NIH budget as a whole--looked at as a measure of the Federal commitment to the support of medical research and education, rather than merely as a catalogue of program estimates--is an encouraging document.

To put the 1972 budget estimates into proper perspective, we must, I think, compare them with the 1970 level of the NIH programs. As you know, we operated during the first half of the current fiscal year (1971)

under a continuing resolution which held the programs to their 1970 levels. The increases over that level only became available for obligation two months ago when the 1971 appropriations were apportioned by the Office of Management and Budget.

I must say, in all candor, that the apportionment was more generous than we had expected. All of the Congressional increases, totaling nearly $147 million, will be available for obligation. The $15 million increase in funds for health facilities construction grants--which remain available until expended--is being held over until next year but all the other increases are available now. And, what is equally important, they have become part of the budget base and were taken into account in preparing the 1972 estimates.

For NIH as a whole, the funds now available for 1971 provide an increase of more than $209 million over the operating level that obtained during 1970 and the first eight months of fiscal 1971. The budget request for fiscal 1972 includes an overall increase of nearly $243 million. If the budget request is approved by the Congress, the total increase in the operating level will thus be a little over $452 million. This is an increase of a little over 31 percent in what is nominally a two-year period. Actually, however, if this appropriation bill comes into effect before the end of this calendar year, a 31 percent increase in funds available for NIH programs will have come about in a little less than a year. The delayed Congressional increases in the 1971 appropriations and the requested increases in the 1972 budget will thus have a combined and cumulative effect on the NIH programs that

marks, I believe, the beginning of a new and more vigorous phase in Federal support for both medical research and education in the health professions.

I am particularly hopeful that it will re-establish lost momentum in the research area. As you well remember, Mr. Chairman, the rapid expansion of biomedical research, for which the Congress was largely responsible, began in 1957 and covered a period of 'seven years of great plenty.' Unfortunately, beginning in 1964, the fortunes of NIH continued to follow that Biblical pattern and we have now had seven lean years. During this latter period, especially during the past four or five years, there has been a slow but steady loss of momentum in existing programs and very little opportunity for the initiation of new ones to take advantage of new leads or to meet new needs. Our main concern has been to hold the line and this became increasingly difficult as the number of projects NIH was able to support continued to shrink due to the combined effects of expenditure restrictions and rising costs--particularly for clinical research involving bed-patients. I believe that this downward trend can now be halted and I am enough of an optimist to hope that we may, once again, be at the beginning of the Biblical cycle.

The 1972 budget estimates for the research Institutes and Divisions are based on 1971 appropriations that were $128.9 million higher than the 1970 operating level and they include requested increases that total an additional $125.6 million. This overall increase of $254.5 million for the research programs represents a 24 percent increase over their operating level in 1970 and the first half of 1971.

The fact that $153 million--or three-fifths--of the total increase in research funds is for cancer research, including the $100 million requested for the new Cancer Conquest Program, will not detract from its effect on the momentum of biomedical research as a whole though it will, to some extent, change its pattern and directions--as, indeed, is the intent. Nearly doubling the funds available for cancer research reflects a choice of priorities--the recognition of a major national health concern and a determination to take advantage of what are thought to be new opportunities for making progress in the attack on cancer. Dr. Baker, the Director of the National Cancer Institute, will testify in detail about these opportunities.

The fear that so much emphasis on a particular group of diseases will distort or detract from research on other serious health problems, while not without foundation, can be exaggerated. Many factors, besides the availability of financial support, determine the directions of research: the existence or absence of enticing 'leads' for further exploration; the scientific background, professional experience, and personal interests of the investigator; the opportunities for research, in terms of available facilities and, in the case of clinical research, an adequate supply of patients with the disease in question; and, in many cases, the intellectual challenge of a particular problem. I doubt that the interplay of these factors has ever produced a 'balanced' pattern of research--if, indeed, 'balance' could be defined in this context. Nor do I think that balance is important in research. The research programs of each of the Institutes must be judged on their own merits. The size of the Federal investment in various fields of research must be based on the

magnitude of the health hazard with which they are concerned, on the importance that the American public attaches to the mitigation or elimination of these hazards, and on the scientific opportunities that are at hand for fruitful research. The latter is particularly important because it is as foolish to force-feed a field in which there are very few leads as to starve a field in which leads are waiting for exploitation. The balance with which we should be most concerned is that between research opportunities and the availability of resources for their exploitation. The funds provided for the uncertain business of probing the unknown in relation to disease problems should reflect the state-of-the-art in the various biomedical disciplines and clinical research fields rather than well-intentioned but extraneous decisions based on political, economic or social factors.

Moreover, cancer research should not be viewed as an isolated--or isolatable--activity. The most important reason for keeping the Cancer Conquest Program within the family of the National Institutes of Health is that cancer research is inescapably intertwined with various aspects of the research missions of the other Institutes. The complex questions to which biomedical research must address itself and the work that goes into their solution are almost never unique to a particular disease or confined to single scientific disciplines.

The present excitement about the role of viruses in causing cancer--which is one of the reasons for feeling that the time is ripe for a Cancer Conquest Program--illustrates the way in which progress in one field of research depends on work being done in another. Virologists,

who for years have been mainly concerned with unravelling the mysteries of infectious diseases, such as the common cold, for which viruses are thought to be responsible, have provided the leads and are now doing much of the work in viral carcinogenesis. Further refinement of this work is now leading deep into the basic sciences of molecular biology and genetics. For example, a very important development of the past year is the discovery that the cell chemical known as DNA is not the sole and unique determinant of genetic patterns it was heretofore thought to be. It has now been shown that RNA, the chemical messenger that carries instructions inherent in DNA's 'code', can, in some cases, dictate how DNA is formed and thus itself control the cell. A series of rapid developments led to the discovery that an enzyme that uses RNA as a blueprint to make DNA is present in more than 30 different viruses that can cause various forms of cancer in birds, mice, cats, and monkeys. Last November one of our own scientists reported that he had found this enzyme in the white blood cells of patients with acute leukemia and it has since been found in patients with breast cancer. It is also known that certain classes of drugs inhibit the activity of this enzyme, at least in the laboratory. However, the next link in this very promising chain of events was the disappointing discovery that the enzyme can also be found in normal cells--which poured cold water on what had been a very hot lead in the search for the mechanism by which a virus can cause some forms of cancer. But further research now seems to show that there is a significant difference between the enzyme found in normal cells and that found in malignant cells--and the trail is once more warm.

In so complex a field as medicine in which so much basic information is still lacking, progress frequently involves a few steps forward and a few steps back. For this reason, the aspect of the Cancer Conquest Program that concerns me most is the danger of overpromise--a concern, Mr. Chairman, which I know you share. The progress that has been made in cancer research in recent years is impressive and highly encouraging. It has, as the President said in his Health Message, opened "many new lines of inquiry and many new opportunities for breakthrough." But he wisely pointed out that the technological challenge of the space program holds no parallel for the more basic scientific challenge of biomedical research and he added that "scientific breakthroughs. . . often cannot be forced--no matter how much money and energy is expended." That is a point of which the public should be constantly reminded.

In previous appearances before this Committee I have emphasized the indispensability of research in the basic biomedical sciences to future progress in applied clinical research on human disease problems. As Sir Francis Bacon said more than 350 years ago, "Knowledge and human power are synonymous, since the ignorance of the cause frustrates the effect". In

the field of medicine, the painstaking and often frustrating burden of assembling the necessary knowledge still rests largely with those engaged in so-called basic research. As the public and national purpose of the research Institutes of NIH is to promote the health of the American people through research, they must maintain a judicious balance between empirical, frontal attacks on disease problems--which do sometimes yield practical, though often imperfect, results--and the more analytical and circuitous search for an understanding of the nature of disease. Clearly, the NIH programs must be responsive to national aspirations but the response must not be allowed to deflect them from the dogged pursuit of the scientific knowledge which alone can lead to real solutions of disease problems. As Prof. Joel H. Hildebrand, the eminent chemist at the University of California, has said: "Science is not a sacred cow that sometimes works miracles, but a work-horse that carries loads."

Among the basic science activities of special importance at this stage in the evolution of medical knowledge is genetics research for which this Committee provided an additional $10 million to launch a special program of project grants. In accordance with the Committee's wishes, I appointed an Inter-Institute Coordinating Committee on Genetics chaired by Dr. Berliner, Deputy Director for Science, and consisting of the Directors of the National Institute of General Medical Sciences, the National Institute of Child Health and Human Development, the National Institute of Allergy and Infectious Diseases and the National Institute of Arthritis and Metabolic Diseases, and Dr. Lamont-Havers, Associate Director for Extramural Research and Training. This committee has recommended that

awards be made for 162 applications that have been approved and given high priority by the Advisory Councils of seven of the Institutes. These awards will total $7,750,000 bringing the amount invested in the genetics program this year to about $60 million. The increase provided by this Committee has made it possible to fund all high-priority applications in genetics of which we previously had a considerable backlog. Dr. Stetten, who rejoined NIH last fall as the new Director of the National Institute of General Medical Sciences which has the major responsibility for the genetics program, will be glad to answer any questions you may have about the future course of these activities.

In addition to the basic biomedical sciences, there are many areas in more immediately disease-related research in which a number of the Institutes share a common interest. One such area is sickle cell anemia, an hereditary blood disease that is one of the most common long-term illnesses among black children and young adults. No permanently effective treatment has yet been discovered and most of the victims of sickle cell anemia die before their 30th year. One of the scientists on the intramural research staff of the Arthritis Institute has done pioneer work on the molecular nature of this disease and four Institutes are at present supporting research on sickle cell anemia through their grant programs:

. . . the Arthritis Institute which supports work focussed on the metabolic nature of the disease;

. . . the Heart and Lung Institute which is concerned with blood abnormalities;

. . . the National Institute of General Medical Sciences which supports research on the basic biochemistry involved; and

. . . the Child Health Institute which is concerned with the diagnosis and treatment of childhood diseases.

Their total investment this year is about $1.5 million. Because of the importance of this disease to the black community and because there has recently been a promising advance in the management of acute crises of sickle cell anemia, the budget request for the Heart Institute includes an additional $5 million to expand work in this area by all of the interested Institutes. I appointed a small Task Force, representing the three Institutes most directly concerned, which drew up plans for the expanded Sickle Cell Anemia Program that the President announced in his Health Message. Dr. Cooper will be glad to describe this program in more detail.

Another area that spreads well beyond the interests of a single Institute is in research on the type of hepatitis that sometimes results from blood transfusions or the use of blood products. Here, I am happy to say, we seem to be on the verge of major advances. You may have seen recent newspaper stories about preliminary reports from Dr. Saul Krugman of New York University which indicate that it may now be possible to develop a vaccine for this type of viral hepatitis which causes about 50,000 illnesses a year. There have also been some promising developments in devising tests to determine whether blood is free of this hazard. Six components of NIH are involved in research on hepatitis:

. . . The Division of Biologics Standards is reponsible for establishing and maintaining standards of quality and safety for all biologic products which, of course, includes human blood for transfusion, products prepared from blood, and the test materials and methods used to assure that they meet the required standards.

. . . The National Blood Resource Program of the National Heart and Lung Institute is responsible for improving blood resources and their usage, including the development of new technology to ensure the safety of these uses.

. . . The National Institute of Allergy and Infectious Diseases is responsible for research on the causative agents of viral hepatitis, for development of new methods for detecting hepatitis virus, for vaccine development and for the production and distribution of reference reagents.

. . . The National Institute of Arthritis and Metabolic Diseases has a general responsibility for research in liver diseases including clinical diagnosis, medical management and the fundamental processes underlying these diseases.

. . . The Clinical Center, which is a major user of blood and blood products, is an intrinsic part of our research effort on hepatitis.

. . . Finally, the broad virologic and immunologic capabilities of the National Cancer Institute are being called on to help solve some of the basic problems involved as well as to assure that new vaccines are free of tumor-inducing viruses.

In addition to the scientific problems, the elimination of the hepatitis risk in blood transfusions will involve complex logistical and legal problems. I have therefore appointed a Task Force on Hepatitis to coordinate the activities within NIH and to mesh these with the responsibilities of other agencies, both Federal and non-Federal.

I shall leave to the Directors of the Institutes the task of setting forth the purposes of the increases in the estimates for the various NIH research programs. It may, however, be useful to summarize for you major changes in NIH research activities as a whole. In addition to the program increases I have already mentioned, a net increase of $9.6 million is requested for the National Institute of Child Health and Human Development for family planning and population research. An increase of $5.3 million is requested for the general expansion of the activities of the still relatively new National Institute of Environmental Health Sciences of which Dr. David Rall is the new Director, succeeding Dr. Paul Kotin who has left us to become Vice President for Health Sciences of Temple University.

For our regular research-grant program, there is a net increase of $18.4 million in the budget. However, as an additional $23 million will be required to honor our moral commitments to ongoing projects, there will be a decrease of $4.6 million for new grants or the renewal of grants beyond their present commitment. There is also a $5 million reduction in the funds requested for the General Research Support Grants of which $2 million reflects the discontinuation of the Health Sciences Advancement Awards which were part of this program.

A decrease of $7 million for fellowships in part reflects the planned phase-out of predoctoral fellowships. In general, the policy is to hold the postdoctoral and special fellowships to slightly below their 1970 level. Due to the Congressional increase in fellowship funds for 1971, the actual number of these fellowships awarded with 1971 funds will be a little higher than in 1970-- 1,499 instead of 1,385. The budget estimate for 1972 allows for only 1,020 of these fellowships so that the average for the two years will be only slightly below the 1970 level. In other words, Mr. Chairman, the number of people holding postdoctoral and special fellowships will be roughly the same in 1970, 1971 and 1972.

In accordance with the agreement of the Office of Management and Budget to defer any modifications of the training grant programs until the training study now under way has been completed, there is no change in the amount requested for training grants. An apparent reduction of

$23 million for the training programs, in some budget tables, is due to the transfer of that amount--which represents the faculty-salary component of the training grants--from the Institute appropriations to the health manpower appropriation. The amounts for faculty salaries in all research training grants awarded to an institution will be paid by the Bureau of Health Manpower Education, in a lump sum, to the dean so that he will have some flexibility in the use of these funds.

Since last year's hearings, much thought has been devoted to the development of national policies for health manpower. The Administration's study of health options for the Nation came to the conclusion that more health manpower, more evenly distributed geographically, is an essential prerequisite if we are to have a national policy of providing equal access to high-quality health care for all Americans. The Carnegie Commission's report on *Higher Education and the Nation's Health--Policies for Medical and Dental Education* has made a number of thoughtful recommendations and has provoked much discussion of the effect of health personnel shortages on our health-care problems. Partly as a result of these two studies, the Administration has proposed legislation to stimulate the production and better distribution of more health professionals.

The health manpower program of NIH are based on four pieces of authorizing legislation. Two of these--the *Allied Health Professions Personnel Training Act* and the provisions in the *Public Health Service Act* relating to public health training--were renewed last year for a further three years. The other two--the *Nurse Training Act* and the

Health Professions Educational Assistance Act--expire on June 30 and their revision and renewal is, as you know, now under consideration by the Subcommittee on Public Health and Welfare of the House Committee on Interstate and Foreign Commerce. The Administration's proposals for the revision of these two pieces of legislation involve a number of important changes in policy and in approach--notably in regard to institutional support and student assistance--which Secretary Richardson has already discussed with you. The budget estimates for the health manpower appropriation reflect these proposed changes. However, a number of alternative bills have also been introduced and I understand, Mr. Chairman, that you have decided to defer consideration of the budget estimates for health manpower until the nature of the authorizing legislation is clear. I shall therefore not comment further on the health manpower programs at this time. However, both Dr. Endicott, the Director of the reorganized Bureau of Health Manpower Education, and I shall be happy to answer any questions you may have about the existing manpower programs or the proposals for their continuation and revision.

There are only modest increases in the budget request for the National Library of Medicine: $471,000 over the 1971 budget authority and $2.2 million over 1970 operating level. Of the increase provided in the 1971 appropriation,

$500,000 was earmarked for the development of plans for the Lister Hill National Center for Biomedical Communication which the Congress authorized two years ago in honor of Senator Lister Hill who, during his long service in the Senate, did so much to promote Federal health activities and, particularly, medical research. The National Library of Medicine, whose role is very much broader than that usually brought to mind by the word 'library', is an essential adjunct to the research activities of NIH. It plays a major part in the very important--and very difficult--task of making research results readily available to health practitioners and to other researchers. In carrying out this task, the National Library of Medicine--under the dynamic leadership of its Director, Dr. Cummings--has gone far beyond the traditional archival functions of a library to become, in fact, a national communications center for biomedical information.

As I said at the beginning of this statement, the budget estimates for the fiscal year 1972 do not answer all our prayers and they will not meet every need that someone in the biomedical community--or, indeed, on the administrative staff at NIH--regards as urgent and important. But this is inevitable and, in some degree, always has been and always will be true. I am satisfied, Mr. Chairman, that this is not only a good budget but that it provides for a real resumption of initiative in the research area and that the amounts requested--and the purposes for which they are requested--will greatly stimulate progress both in health research

and in the provision of adequate health manpower. If the increases in the NIH budget since I appeared before this Committee last year are, indeed, the harbingers of future support, we can look forward to another rewarding period of growth in the advancement of the health of the American people.

TAB 11

OUTLOOK FOR NIH SUPPORT OF
MEDICAL EDUCATION AND RESEARCH

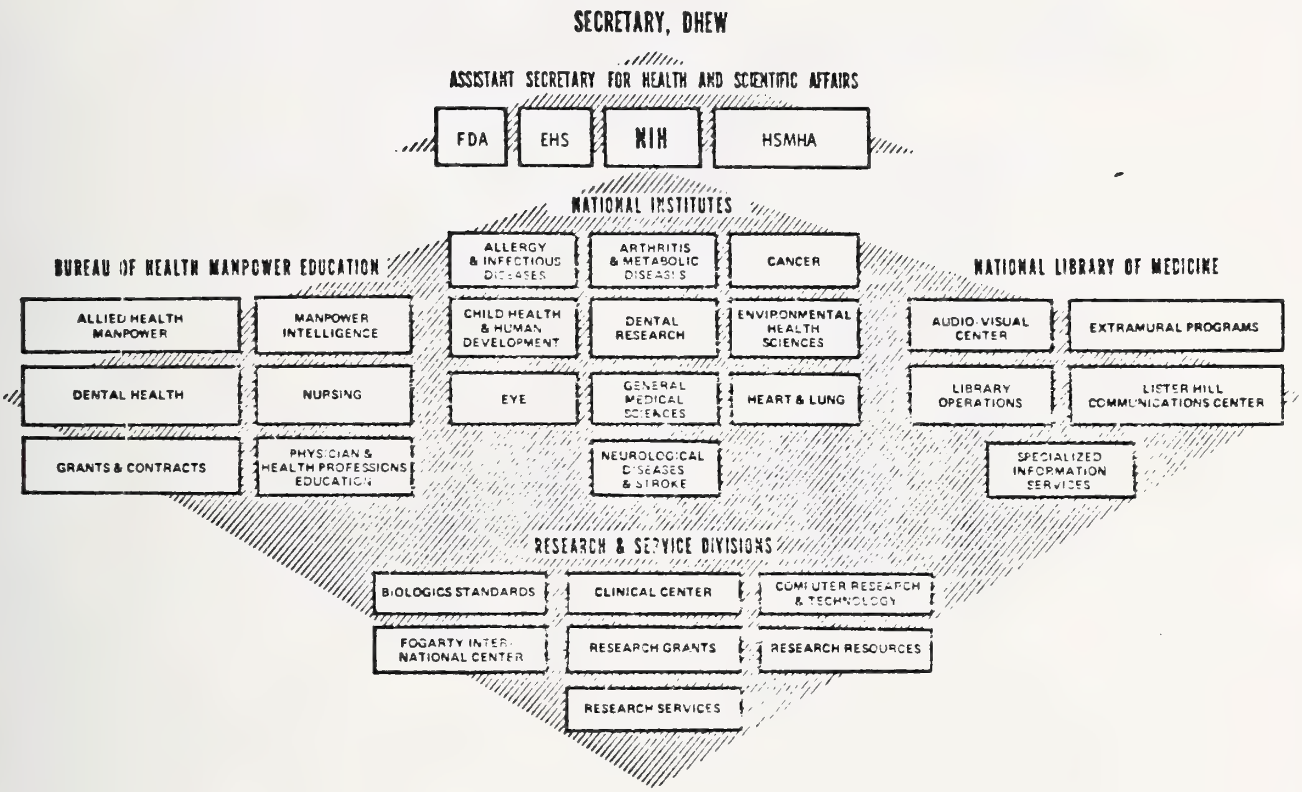
Background Information[1]

Robert Q. Marston, M.D.[2]

[1]Prepared for meeting of the Association of Professors of Medicine, Atlantic City, New Jersey, May 1, 1971.

[2]Director, National Institutes of Health, U.S. Department of Health, Education and Welfare.

I. ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH



The principal changes over the past year in the operating organization of the health agencies reporting to the Assistant Secretary for Health and Scientific Affairs, DHEW, affected mainly the Environmental Health Service and stemmed primarily from the creation of a new executive agency reporting directly to the President--the Environmental Protection Agency. These changes are as follows:

- Transfer from DHEW to the new agency of air pollution control, water hygiene and solid waste management programs, some functions relating to pesticides, and certain portions of the radiological health program.

- Retention in DHEW of programs to improve the environment of communities, occupational health and safety, the Arctic Health Center, and activities relating to the medical effects of radiation in DHEW (The decision on how these remaining functions will be organized and the disposition of the Environmental Health Service has not been made as of this date).

Within NIH, the major organizational changes are as follows:

- The complete internal reorganization of the Bureau of Health Professions Education and Manpower Training based on program purpose and legislative authority and the renaming of the organization as the Bureau of Health Manpower Education.
- The return of the Division of Research Resources from the Bureau to the research component of NIH and its former status as a separate Division along with the Institutes and other Research Divisions.

The top staff is as follows:

Director	Dr. Robert Q. Marston
Deputy Director	Dr. John F. Sherman
Deputy Director for Science	Dr. Robert W. Berliner
Director, Bureau of Health Manpower Education	Dr. Kenneth M. Endicott
Director, National Library of Medicine	Dr. Martin M. Cummings
Associate Director for Health Manpower	Dr. Leonard D. Fenninger
Associate Director for Program Planning and Evaluation	Dr. Thomas J. Kennedy, Jr.
Associate Director for Administration	Mr. Richard L. Seggel
Associate Director for Communications	Mr. Storm Whaley
Associate Director for Clinical Care Administration	Dr. Thomas C. Chalmers
Associate Director for Extramural Research and Training	Dr. Ronald W. Lamont-Havers
Assistant Director for Collaborative Research	Dr. Leon Jacobs

II. THE CURRENT YEAR (FISCAL YEAR 1971) BUDGET

A. Chronological Development

For the first seven months of this fiscal year, NIH, like other agencies of the DHEW, operated under the provisions of a continuing resolution of Congress, which restricted operations to last year's level. However, the fiscal year 1971 appropriations bill, which provides substantial increases in funds for NIH, was passed by Congress and approved by the President on January 11, 1971. Thus, these substantial increases for NIH are, in a practical sense, available for use in no more than five months during the current fiscal year. Following is a table which shows the progression of the current year budget (in terms of pluses and minuses) in comparison to last year's budget.

(In thousands)

Activity	F.Y. 1970 Actual	Fiscal Year 1971 Changes Over 1970: President's Budget	Congr. Approp.	1971 Column of 1972 Budget*
Institutes & Research Divisions				
Research grants...............	$592,689	+$15,030	+$79,821	+$74,103
Training grants & fellowships	155,971**	-1,732	+10,730	+3,289
Collab. res.(mostly contracts)	127,088	+43,072	+58,384	+55,905
Intramural research..........	90,302	+9,539	+13,401	+15,598
Other direct operations......	46,471	+2,850	+3,423	+4,843
Subtotal, IRD's............	1,012,521	+68,759	+165,759	+153,738
Bureau of Health Manpower Educ.				
Medical, dental and related health professions.........	301,204**	-1,883	+35,877	+22,377
Nursing.....................	50,259	+15,249	+24,749	+23,249
Public health................	17,970	-969	+531	+531
Allied health................	13,407	+6,080	+6,080	+6,080
Prog. dir. & manpower anal...	5,020	+252	+252	+252
Other........................	13,515	-10,432	-10,432	-10,432
Subtotal, BHME.............	401,375	+8,297	+57,057	+42,057
National Library of Medicine...	19,979	+302	+1,302	+1,531
Other..........................	10,058	+7,307	+7,307	+7,543
Total, NIH..............	1,443,933	+84,665	+231,425	+204,869

*Reflects pay increases.

**Reflects comparative transfer of $23,000,000 for the salary components of research training grants in health professions schools from the Institutes to the Bureau of Health Manpower Education.

B. Explanation

1. The President's 1971 budget, submitted a year ago, provided for the following:

a. An increase over fiscal year 1970 of $68.8 million for research or about 6 percent, reflecting:

(1) Significant increases for cancer ($22.6), family planning and population research ($12.8), early childhood development ($6.5), heart and lung diseases ($13.0), and dental research ($5.9);

(2) A hold-the-line policy on research training grants, pending the outcome of a study of this program; and

(3) A 20 percent decrease ($10.5) in general research support grants.

b. A net increase of $8.3 million for health manpower education, reflecting:

(1) Increases of $22.2 million for grant support to schools of medicine, dentistry and osteopathy, schools of nursing, and institutions providing allied health training;

(2) A decrease of $3.5 million for student assistance based on the assumption that scholarships and direct loans should go for the most part to students from families with incomes below $10,000 and that students from higher income families should take advantage of the loan guarantee program of the Office of Education; and a decrease of $0.6 million in public health traineeships.

(3) A decrease of $3.1 million for the elimination of basic improvement (formula) grants to schools of veterinary medicine and reductions in grants for graduate public health training; and

(4) A reduction of $23 million in total obligational authority for construction grants to health professions schools and the anticipation that support of construction of teaching hospitals would be shifted to a loan guarantee method of financing (with Federal subsidy) through the Hill-Burton program.

c. Maintenance of the National Library of Medicine's programs at approximately the previous year's level.

2. Congressional action on the appropriation bill, as compared to the President's budget, provided for the following:

a. A further increase of $97.0 million for research, reflecting:

(1) Increases above the President's budget for cancer ($28.0 million), heart and lung diseases ($21.7 million), stroke in the National Institute of Neurology and Stroke ($8.8 million), and genetics in the National Institute for General Medical Sciences ($10 million); and

(2) Across-the-board "cost of living" increases of $38.5 million designed to bring research activities, including the research training programs and the general research support grant programs, up to the 1970 "program level."

b. Increases for the Bureau of Health Manpower Education of $48.8 million, including:

	(Millions)
Medical, dental and related institutional support (including restoration of $2.7 million for base grant support of schools of veterinary medicine)	$10.7
Nursing institutional support	0.5
Public health training programs	1.5
Medical, dental and related scholarships	0.5
Medical, dental and related student loans	13.0
Nursing student loans	7.5
Construction--of which $1.5 million was for nursing school construction; the remainder for medical, dental and other health professions schools	15.0
Division of Dental Health research grants	0.1

c. A $1.0 million increase in the National Library of Medicine, with $0.5 million for the Lister Hill National Center for Biomedical Communications and $0.5 million spread among the other Library programs.

3. The amounts of the fiscal year 1971 appropriations which will be made available through the apportionment process reflects the utilization of the following to cover the deficiency which resulted from increased pay costs. (All funds were used within NIH except $1.9 million transferred to St. Elizabeths Hospital):

a. Congressional increases of $7.5 million for research training grants ($0.8 million of the $7.5 million in the Cancer and Heart appropriations will be reprogrammed for purposes other than pay raise or training); this reflects the hold-the-line policy pending the outcome of the study.

b. $6.5 million of the Congressional increase of $12.9 million for general research support grants ($1.9 million in the Cancer and Heart appropriations to be reprogrammed within these appropriations for uses other than pay increases).

c. $2.25 million from the $10 million Congressional increase for genetics and $2.25 million from the Congressional increase for stroke.

(Note: The use of $15 million Congressional increase for construction grants to medical, dental and other schools will be deferred to fiscal year 1972.)

Activity	(In thousands) 1971 Column Comparable	1972 Estimate	Change
Institutes and Research Divisions			
Research grants	$666,792	$685,341	+$18,549
Training grants and fellowships	159,260*	152,239*	-7,021
Collaborative res.(mostly contracts)	182,993	186,758	+3,765
Intramural research	105,900	113,394	+7,494
Other direct operations	51,314	54,109	+2,795
Special cancer initiatives	....	100,000	+100,000
Subtotal, IRD's	1,166,259	1,291,841	+125,582
Bureau of Health Manpower Education			
Medical, dental and related health professions	323,581	434,045	+110,464
Nursing	73,508	67,000	-6,508
Public health	18,501	18,544	+43
Allied health	19,487	30,654	+11,167
Program direction & manpower anal	5,272	6,682	+1,410
Other	3,083	4,000	+917
Subtotal, BHME	443,432	560,925	+117,493
National Library of Medicine	21,510	21,981	+471
Other	17,601	18,423	+822
Total, NIH	1,648,802	1,893,170	+244,368

*Reflects a comparative transfer in each year of $23,000,000 from the Institutes to the Bureau of Health Manpower Education for the salary components of research training grants awarded to health professions schools.

Highlights of the 1972 Budget

The President's 1972 budget for NIH provides an overall increase of over $244 million, or 15 percent, over fiscal year 1971 and $449.2 million, or 31 percent, over fiscal year 1970.

1. Research: The requested net increase for research over fiscal year 1971 is $126 million, or 11 percent. Compared to fiscal year 1970, which is essentially the level at which NIH has been operating for the first seven months of the current fiscal year, the budget increase for research totals $279 million and amounts to an increase of 28 percent. The major features of the budget for research are:

a. An increase over fiscal year 1971 of $100 million for a special, targeted attack on cancer, which is in addition to a $50 million increase provided in the current year for the research activities of the National Cancer Institute (the major aspects of the $100 million new initiative were presented in the President's Health message); the present plans provide for the use of $25 million of these funds beginning this fiscal year through the mechanism of advance obligational authority; in this manner, launching of the attack may begin prior to passage of the 1972 appropriation;

b. An increase of $5 million for research in sickle cell anemia to be funded through the National Heart and Lung Institute (Note the NHLI budget in fiscal year 1971 contains an increase of $34 million over fiscal year 1970, mainly for arteriosclerosis and lung research);

c. Increases in other special initiative areas, including over $9 million for family planning research, $5 million for environmental health sciences, and $3 million for dental caries research;

d. Increases of $23 million for non-competing continuation research grants ("moral commitments");

e. Decreases totaling $41.6 million in other research areas considered to be of lesser priority--e.g., general research support grants, artificial heart and kidney programs, perinatal studies, drug coronary study, regular research grants and intramural research in non-initiative areas, and fellowships; and

f. A shift of $23 million attributable to the health professions school salary components of the research training grants programs of the several Institutes to the Bureau of Health Manpower Education; the objective is to support the current level of research training pending the outcome of the training study (now scheduled for completion in September 1971) but to do so in such a way as to put more flexible means of control in the hands of the school Deans.

2. Health manpower education: The President's 1972 budget provides a total increase of approximately $117 million over 1971 and $150 million over the 1970 level for health manpower education. The major features are:

a. A net increase over fiscal year 1971 of $114.5 million for support to medical, dental and related health professions schools, reflecting:

(1) A $113.0 million increase for institutional support*
(2) A $6.25 million decrease for direct loans to students
(3) A $13.4 million increase for scholarships
(4) A $1 million increase for dental programs, including fluoridation and training in the use of dental auxiliary personnel

b. A net decrease of $6.5 million for schools of nursing consisting of:

(1) A $7.5 million decrease in direct loans to students
(2) A $1.0 million increase in training of teachers, supervisors and administrators
(3) A $1.0 million increase for nurse refresher training
(4) A $0.5 million increase for supporting activities

(The fiscal year 1971 budget shows a net increase of $23.2 million for nursing over fiscal year 1970.)

c. A net increase of $11.2 million in the allied health programs, reflecting:

(1) An increase in institutional support of $0.25 million
(2) An increase of $10.25 million in special projects for experimentation, demonstration, and institutional improvement related to training or retraining of allied health personnel
(3) An increase of $0.5 million for staffing regional offices

d. A $16.0 million decrease in construction assistance to health professions and nursing schools

3. National Library of Medicine: This appropriation is being maintained at about the 1971 level (which reflects a $1 million increase over 1970).

*This is in addition to the $23 million transfer of research training funds from the Institutes, which is reflected in the budget "base" of the Bureau of Health Manpower Education (i.e., in the 1970 and 1971 columns as well as the 1972 estimate).

IV. FEDERAL BUDGETS FOR MEDICAL R&D, FY 1970-1972
(in millions)

Agency	1970 actual	1971 est. obligations	1972 est. obligations	increase 1972/71	Percent increase
Total	$1,664	$1,933	$2,087	$154	8
VA	59	62	62	-	0
DoD	125	117	122	5	4
AEC	104	105	104	-1	-1
NASA	86	103	78	-25	-24
NSF	28	30	32	2	7
DHEW 1/	1,177	1,324	1,438	114	9
(NIH)	(873)	(1,039)	(1,168)	(129)	(12)
Agriculture	50	55	56	1	2
Environmental Protection Agency	-	85	100	15	18
Other	35	52	95	43	83

1/ For FY 1971 and FY 1972, excludes those research programs transferred to the Environmental Protection Agency, December 1970

Note: Covers support of medical and health-related R&D (projects, resources, and general support including PL 480 funding for research) but not training or construction

V. LEGISLATION AND PENDING BILLS AFFECTING NIH'S ORGANIZATION

Health Manpower Legislation

Health Professions Educational Assistance

There are three major proposals so far, offered by the Administration, the Association of American Medical Colleges and the Federation of Schools of the Health Professions, and Representative Paul Rogers (D-Fla.).

The Administration proposal (H.R. 5614, Staggers; H.R. 5767, Nelsen and others; and S. 1183, Javits) would provide for capitation grants of $6,000 per graduate for schools of medicine, osteopathy, and dentistry, with adjustments for student transfers and shortened curricula. It would provide separate authorities for special project grants to schools of medicine, osteopathy, and dentistry; schools of pharmacy, optometry, podiatry, and veterinary medicine; and schools in financial distress. Added are authorities for grants to aid disadvantaged students and to improve area or specialty distribution of manpower and for traineeships in medicine, osteopathy, and dentistry.

A new authority for Health Manpower Education Initiative Awards would permit grants for a variety of purposes, including establishment of area health education centers, training for better health care delivery in the context of the team approach and health maintenance organizations, and the like.

A consolidated construction authority (manpower, medical libraries, and health research) is provided, including authority to make grants (up to 67%), and guarantee loans, and pay up to 3% interest subsidies in the case of private sponsors.

The loan ceiling for health professions students is increased from $1,500 to $5,000 annually under the Higher Education Act of 1965. The bill liberalizes repayment terms and includes Federal repayment of loans to students who practice in health manpower shortage areas or certain specialties in short supply. Also forgiven are loans to students of medicine, osteopathy, dentistry, or nursing who are from low-income or disadvantaged families and who fail to complete their health studies.

The existing scholarship programs for health professions students, which are due to expire at the end of the current fiscal year, are extended for three years. The bill also makes discretionary the present mandatory program of grants for scholarship aid to schools of optometry, podiatry, pharmacy, or veterinary medicine, but continues grants to schools of medicine, osteopathy, and dentistry on the present mandatory footing. It increases maximum health professions scholarships from $2,500 to $3,000 and limits scholarships to exceptionally needy students from low-income or disadvantaged families.

The bill authorizes appropriation of such sums as necessary for the above purposes.

The AAMC proposal (H.R. 4171, Staggers; S. 934, Kennedy) would also provide capitation grants, at the level of $5,000 per student for schools of medicine, osteopathy, and dentistry; $3,500 for optometry, podiatry, and veterinary medicine, and $2,000 for pharmacy. It raises the schools' base grant from $25,000 to $50,000 and authorizes such sums as necessary for formula support. Special project grant authorization for 1972 is $150 million.

The bill would extend existing construction authority for five years, authorizing $300 million for 1972. It would raise the student loan ceiling to $3,500 per year and extend forgiveness provisions to all HPEA professions. It raises the maximum annual amount of scholarships from $2,500 to $3,500 and increases the allotment factor from $2,000 to $3,000 times 10% of enrollment.

A second AAMC proposal (H.R. 4170, Staggers; S. 935, Kennedy) would authorize grants for start-up, construction, and initial operating costs for new or significantly expanded schools of medicine or osteopathy; grants to assist academic health centers in planning and initiating health maintenance organizations; and grants to assist in the establishment of area health education centers.

The Rogers proposal (H.R. 4155) eliminates the base grant to schools and substitutes a $3,500 capitation formula for all enrolled HPEA students. Special project authorization is $105 million for 1972.

Construction authorities (other than health research facilities) are extended for three years, with a 1972 authorization of $325 million. The health research facilities authority is replaced by a new graduate training grant authority for which $10 million is authorized in 1972.

The Rogers student aid proposal is essentially similar to that of the AAMC, except that forgiveness of any educational loan is provided for physicians, dentists, or podiatrists who contract to practice three years in a shortage area.

Nursing

There are two major proposals: the Administration bill (H.R. 5614, above) and Representative Rogers' bill (H.R. 4618). Other bills have been introduced but were not available at this writing.

The Administration bill deletes the authority for construction of nurse training facilities (it is included in the proposed new consolidated construction authority). It would not extend the authority for formula grants but would extend special project grants for three years, adding specific authority to train, or develop training for, new levels or types of nursing or related skills, and to promote full utilization of nursing skills.

It would extend for three years the program of advanced traineeships for professional nurses, and authorize such sums as necessary for such purposes. It would broaden the authority for contracts and grants to identify potential nursing candidates and encourage them to undertake nurse training or retraining.

The Rogers bill (H.R. 4618) would continue the formula grant authority with a grant of $2,000 per full-time enrolled student and would authorize $20 million in special project grants for 1972. It authorizes $40 million in construction grants for 1972.

It would continue the traineeship authority, raise the student loan ceiling from $1,500 to $2,500, and allow forgiveness of up to 100%. The allotment formula for scholarships is increased from $2,000 to $3,000 times enrollment.

Other Pending Bills

Proposed National Cancer Authority

The Chairman of both the House and Senate Committees having jurisdiction over health legislation introduced bills in December 1970 [S. 4564 (25 co-sponsors), H.R. 19966, and four other House bills] calling for a transfer of employees, contracts, property, and resources from the NCI to the National Cancer Authority. The NCI and National Cancer Advisory Council would "lapse."

On January 26, 1971, Senator Kennedy, new Chairman of the Senate Health Subcommittee, introduced S. 34, the "conquest of Cancer Act," which would also transfer NCI's functions to a National Cancer Authority. The bill now has 52 co-sponsors. Twelve similar bills with more than 100 co-sponsors were introduced in the House. Hearings were held on S. 34 on March 9 and 10, 1971.

Proposed National Kidney Disease Act

Forty members of the Senate and 113 members of the House co-sponsored identical bills in the 91st Congress (S. 2482, H.R. 12425, and others) to amend the PHS Act by adding a new title, "Title X--Education, Research Training, and Demonstrations in the Field of Kidney Disease."

No hearings were held on these bills. Although the scope of RMP has been expanded to include kidney and other related diseases (P.L. 91-515, October 1970), no research functions are being transferred from the NIH.

However, six new bills similar to those proposed in the last Congress have already been introduced thus far in the 92nd Congress.

New Institute Proposals

The Second Session of the 91st Congress featured a slackening of the brisk pace at which legislators introduced bills to establish new institutes at the NIH. None of the proposals advanced far in the Congressional process. However, the 92nd Congress has already generated a number of bills directly affecting NIH functions.

National Kidney Institute

H.R. 497 - Whalley, 1/25/71

National Institute of Marine Medicine and Pharmacology

H.R. 547 - Downing, 1/25/71

National Institute of Digestive Diseases and Nutrition

S. 305 - Kennedy, 1/26/71
H.R. 3665 - Staggers, 2/4/71
H.R. 4837 - Hanna, 2/23/71

National Institute of Gerontology

H.R. 188 - Jacobs, 1/22/71
S. 887 - Eagleton, 2/19/71

H.R. 4979 - Jarman, 2/25/71
H.R. 6405 - Thone, 3/18/71

Enacted Legislation

Occupational Safety and Health Act of 1970

This broad legislation which was recently signed into law (P.L. 91-596) provides for promulgation and enforcement of standards, largely through the Department of Labor. It also provides, for the first time, a specific statutory basis for DHEW's activities in the field of occupational health and safety.

The Director of the National Institute of Occupational Safety and Health will have authority for the study of specific diseases within the dimensions of the occupational environment, although, in a general sense, responsibility for the study of these diseases is already vested in the various Institutes within the NIH (particularly the NIEHS), as well as in other HEW agencies. For instance, laboratory studies on chronic low-level exposure in the occupational environment are virtually identical with those in the general population. Another example is the problem of pulmonary diseases in the occupational environment (NIOSH) versus the general environment (NIEHS and NHLI).

TAB 12

A Strategy For Our Nation's Health*

Robert Q. Marston, M. D.
Director
National Institutes of Health
U.S. Department of Health,
Education, and Welfare

I was highly complimented when your vice-president, Mr. Laise, invited me to share in your convention session on "The Evolving Role of the Red Cross in the Health Field." We are all aware of the close relationship the American Red Cross and the National Institutes of Health have enjoyed through the national blood program, and it is a pleasure to join you today.

Your agenda calls for a discussion on innovations in community services. How appropriate for an organization whose entire history is replete with innovative measures of many types, an organization whose programs have always pointed to the future.

Your services range from special programs to bolster the health and morale of our servicemen assigned to remote outposts overseas to well-designed efforts to increase public understanding of first aid and home nursing care in

*To be presented at the American Red Cross Convention, Washington, D. C., May 17, 1971.

communities across this land. It is little wonder that the American National Red Cross has earned the gratitude and support of the American people.

Your convention theme today -- health and health care -- demonstrates anew your concern with the most vital issues facing our society. These health problems have assumed a front and center stage position in the halls of Congress, reflecting the commanding -- I might even say demanding -- position they hold in communities across the Nation.

Recognizing these problems, seeing them as paramount in their effect on individual Americans, on communities, and on the Nation, the President has mapped a comprehensive health strategy which employs new ways of attacking and solving health and health care problems. The strategy focuses on:

-- Improving the organization, delivery and effectiveness of health care services;

-- Enabling more people to meet the costs of health care;

-- Developing a greater sense of personal responsibility for and individual involvement in health services;

-- Increasing the supply of trained health manpower; and

-- Extending the base of knowledge upon which all health progress rests.

One approach to making health services more flexible as well as more accessible is through Health Maintenance Organizations. In his health message to the Congress, the President identified the Health Maintenance Organization as an essential component in his national health strategy.

In essence, Health Maintenance Organizations provide a comprehensive range of health services to a defined population group at a predetermined fixed rate based on enrollment of the group. This system provides a financial incentive to use costly resources effectively. There is an incentive to prevent disease, to detect and treat illness as early as possible, and to avoid unnecessary hospitalization As the President noted, "cost consciousness is fostered."

To stimulate the development of these organizations, the Administration has proposed planning grants and contracts ranging up to $500,000 per HMO. HMO's that might be established to serve predominantly underserved areas would

be eligible for operation grants for a period of up to 3 years. Loan guarantees would be available for HMO capital costs and working capital, and HMO options would be made available under Medicare and Medicaid, as well as under the proposed Family Health Insurance Program and the Health Standards Act.

Another element of the President's national health strategy relates to the medical manpower problem. HMO's and other innovations will help use this manpower more efficiently, but we still need more health professionals. In this connection, one of the most commonly raised questions is, Why haven't the medical schools expanded their output? The answer is, they have been doing just that since the middle of the last decade. Whereas the number of graduates from schools of medicine and osteopathy rose only from 7,500 to 7,800 during the first five years of the 1960's, it jumped to 8,500 in 1970. And we can reasonably project a greater increase in future years.

Classes entering these schools, numbering about 9,200 in 1965, are expanding by 1,000 or more a year; for example, from 11,000-plus in 1969 to more than 12,000 last year, with an estimated entering class of 13,000 in 1971.

The increase has come about because new medical schools have been started and older one expanded. Grants under the Health Professions Educational Assistance Act of 1963 have enabled more than 65 existing schools to enlarge their classes; meanwhile, 17 new medical schools (including four 2-year schools) have become available. Thus, since September 1967, more than 3,100 first-year places have been added. And seven more new schools are in various stages of planning.

But the finished product, the practicing physician, remains in short supply, despite the fact that the number of physicians has gone up about 12 percent in the last 5 years, while population growth has been about 5 percent. We have the components here for a vicious circle: our supply of physicians is expanding faster than the population, but the demand for health care continues to

outstrip supply -- and thus more and more physicians are needed to close the gap. It reminds one of the theorum in geometry where a variable approaches a constant, but never reaches it.

What about physician's assistants? At present programs are in operation around the country training a new type of physician's assistant capable of taking over much of the physician's clinical routine -- in general medicine, pediatrics, orthopedics, anesthesiology and psychiatry.

Still, numerous medicolegal problems remain to be solved, particularly with regard to how much a physician can properly delegate to a non-physician. State licensing requirements differ considerably. The long-term potential is definitely there, but it seems unlikely that these programs will have any significant impact before the end of the 1970's.

The President has recommended a variety of measures to ease our health manpower plight. They include:

- Capitation grants on the basis of $6 thousand for each <u>graduate</u> to encourage greater output of physicians and dentists.

- Grants, to increase enrollment and shorten curriculum as well as to help schools offer educational opportunities to disadvantaged students.

- A new program (Health Manpower Education Initiative Award) to develop new organizational forms such as consortia and area health education centers.

- Up to $3 thousand a year for low-income and minority group students under the health professions scholarship program, concentrated on students in their first two years of training, after which the guaranteed loan program would be used.

- Funds to increase the numbers of physician's and dental assistants, pediatric nurse practitioners, and nurse midwives. Special efforts will also be made to expand the MEDIHC program which brings servicemen and women into civilian health occupations after they leave the military.

So far my remarks have concentrated on health care and proposals for making it more available to Americans everywhere. But there were other elements in the President's health strategy, elements more important, perhaps, in the long run, because they relate to prevention of sickness and premature death. In his health message, the President spoke of the responsibility each individual bears for his own health.

I know that many groups are aware of this need, starting most notably with the American Red Cross and with the leading voluntary health agencies. But there

is no national instrument to take the leadership for a sustained and coordinated health information campaign.

To fill this void, the President has called for the establishment of a private Health Education Foundation as a national, but not Federally funded, organization. Its objectives would be to enlighten every citizen on the importance of maintaining good health and to motivate him toward appropriate individual and community action.

For the ultimate means to prevent sickness and premature death, however, we must turn to another element in the national health strategy, and one very dear to my heart -- biomedical research. Research will provide not only the means to cure disease but the knowledge for preventing it.

At the present time, the strategy is focusing on cancer, second biggest cause of death in the United States today. You have heard the grim figures -- more than 600,000 new cases of cancer will be diagnosed in our country this year and over 300,000 Americans will die from the disease. And unless the present rates of

incidence can be lowered, one of every four living Americans will someday develop some form of cancer.

Still, earlier diagnosis of certain cancers and new treatments by surgery, radiation and drugs have reduced the inevitability of death from these cancers, once discovered. More than 2 million Americans who have had cancer are alive today because their cancer was discovered and treated. Vigorous treatment of certain leukemias with new combinations of drugs and the use of ultra-sophisticated forms of radiation for the treatment of Hodgkin's disease are two good examples.

"There are moments in biomedical research," the President noted, "when problems begin to break open and results to pour in, opening many new lines of inquiry and many new opportunities for breakthrough." Believing that cancer research has reached such a point, the President requested an additional $100 million for cancer research in his new budget, with a pledge to

"ask later for whatever additional funds can be effectively used."

Last week, in addition, he asked the Congress to establish a "cancer cure program" which will have the full weight and support of the Presidency. To this end, the head of this cancer cure program will report directly to the President. However, the program is to be established within the National Institutes of Health where, as the President stated, "it can take the fullest advantage of other wide-ranging research."

It is important to realize that cancer research has not and cannot be carried successfully on in a vacuum. The gains that have been made have come through research in many disciplines and in other diseases. Some of the research involved probing the chemistry and metabolism of the cells of the body.

And some of this kind of research, basic for acquiring knowledge to cure cancer, is basic also to acquiring knowledge of the many little understood, crippling, youth-destroying diseases which we must also work to cure or, better, prevent.

One of these singled out for special attention is sickle cell anemia, an inherited disease which is found only in blacks or in individuals with Negro heritage. Although its cause was discovered some years ago, no specific permanently effective treatment has been found.

An estimated 50,000 American Negroes have sickle cell disease, of whom at least ten percent require hospitilization for sickle cell "crises" each year. Many others are treated as outpatients in hospital emergency rooms.

At the National Institutes of Health a significant research effort on sickle cell anemia is already under way. For example, the National Blood Resource Program of the National Heart and Lung Institute is awarding contracts for clinical trials testing the efficacy of various types of therapy. Transfusion therapy offers several possibilities for exploration and experimentation, such as infusing normal blood and removing sickled erythrocytes. And a recent finding that fetal hemoglobin seems to offer some protection against sickle cell anemia may also hold promise.

The sickle cell anemia program will be expanded in line with the President's recommendation and the dimensions of the problem.

Hepatitis – Genetic diseases CV diseases

I have presented a very brief outline of our national health strategy. I have omitted much. But I hope I have given you some of its aims and some of the considerations on which they are based.

I would stress, as a final word, that the strategy is national rather than Federal. It depends on the interest

and participation of concerned groups such as yours.

As long as our Nation can count on the cooperation of organizations like the American National Red Cross, and profit from its specific expertise in such areas as community services, nursing care, first aid, drug abuse and drug education, general preventive practices, and the blood program -- and I wish to stress this point particularly -- as long as we can count on your cooperation and assistance in helping communities expand their capacity to cope with their health problems, the burden will be shared equitably and we will move toward a successful solution to our health problems more rapidly.

Thank you.

TAB 13

Maintaining the Momentum of Science *

By Robert Q. Marston, M.D. **

It gives me a great deal of pleasure to take part in these ceremonies and to offer my very hearty congratulations to the winners of the Tomorrow's Scientists and Engineers Awards Program. I want also to congratulate the National Science Teachers Association and the other organizations which had a hand in administering and sponsoring this worthwhile program. Your combined effort serves as an inspiration not only to talented young people everywhere but to those of us well on the other side of the generation gap who are interested in the future of science in a dynamic society.

This award program comes at a time when we are in a nation-wide ferment about the uses, the meaning, and the promise of science in our society. All of science is being asked a basic question -- how can science and technology be applied most effectively to solve the problems of man?

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*To be presented at Recognition Banquet of the Tomorrow's Scientists and Engineers Award Program, Washington, D.C., May 17, 1971.

** Director, National Institutes of Health, U. S. Department of Health, Education, and Welfare.

But the question has a special urgency for the health sciences. The general perception of a "crisis in health care," a crisis in health manpower," and a "crisis in medical schools" constitutes a significant consideration in the outlook for biomedical research in the decade of the '70's. And, of course, it has a special relevance for an agency such as mine whose sole reason for being is the improvement of the health of the American people.

The years since World War II have witnessed a remarkable growth in American science. I would like to trace that growth very briefly, with respect to biomedical science in general and the National Institutes of Health in particular, and then pose some questions which the young winners and their colleagues will be grappling with in the years ahead.

Perhaps the single most significant impetus to American science was the publication 25 years ago of Dr. Vannevar Bush's remarkable and precedent-setting report, Science, the Endless Frontier. Dr. Bush's volume set off a chain of developments that are still in motion today. For example, his principal recommendations concerning medical

research -- Federal financial support for research projects, for research training, and for the institutions which conduct research -- set the pattern which has been followed with great success for a quarter of a century.

The growth of both Federal and national expenditures for research and development was gradual until fiscal 1957, when a sudden expansion brought NIH research support to $125 million. Then, Federal support began to accelerate as Sputniks I and II gave a spurt to all U.S. science.

By 1967--ten years later--Federal support of biomedical research was twice the nonfederal, or about $1.5 billion.

The rapid growth in Federal medical R & D tapered off in the years from 1967 to 1970. There was a plateau in NIH funding, or a decline, estimated as high as 25-30 percent, in terms of program support. This was not compensated by additional support from the private sector. The 1971 budget, however, checked this downward drift by maintaining present program levels and allowing for inflation. It also provided for substantial increases in selected areas such as reproductive biology, environmental health sciences, and cancer, heart and dental research.

A quarter of a century later it can be said that most of the proposals of the Bush report have been carried out with a success exceeding the fondest dreams of those days. But what can be said of the increase in knowledge for the improvement of human health which was the reason for the whole biomedical effort? Quickly and somewhat simplistically, we can answer:

- Dramatic success in the control, prevention, and cure of acute biological events and diseases, such as the whole range of infectious diseases;
- Progress in surgery and related fields;
- Short-term control of physiological and biochemical processes at a very sophisticated level;
- Significant but much more modest success in chronic diseases, and in problems of human development and behavior;
- Provision of a sound scientific capability base for the future.

At the very least the accomplishments of biomedical science in this brief time have changed our whole concept of health and disease, have revolutionized the practice and teaching of medicine, and have raised the level of expectation of the people to a very high point indeed. Yet, the dangers of over-promise are so real that a candid view of the future

requires some caution.

The Biomedical Science Frontier today

Many of the changes that civilization has witnessed in our lifetime have derived from the application of general laws of the physical sciences discovered, applied, and tested by brilliant and creative intellects. In contrast, biomedical science is still only "a scanty patchwork of basic principles that are truly known"--in the words of Paul Weiss, Professor Emeritus of the Rockefeller Institute.

What are today's prospects of biomedical research for attaining a consistent and comprehensive understanding of the phenomena of life? Reviewing the advances of the past in the unraveling of the genetic code, in protein synthesis, in virology, in cell biology and other fields, one can speculate on how long it will be before we can make broad generalizations about the nature of living things.

Such generalizations, however, will almost surely require major achievements in the pursuit of long-sought goals in biological research--ranging from cell differentiation to an understanding of the basic mechanisms of immunity.

In the biosciences, we may have to continue for many years to advance problem by problem and step by step, only rarely rewarded by a discovery as noteworthy as penicillin for infectious diseases or the decoding of DNA as a basis for progress in genetics. I would assert that, in either case, the biomedical frontier today is immensely more promising than 25 years ago. The prospect of using these sciences to improve further the health of mankind is bright indeed.

Basic Questions Reexamined

Vannevar Bush's report focused not only on opportunities for science but on the national role in fostering science for social purposes. His charge was, "With particular reference to the world of science against disease--what can be done now to organize a program?" And secondly, "Can an effective program be proposed for discovering and developing scientific talent in American youth?" These questions have a familiar ring today. Despite the fact that programs have grown rapidly and scientific accomplishment has been dramatic, questions continue to arise regarding public policy in the support of biomedical research and the nature of the central organization of science.

The policy issues have been sharpened with the passage of years and more recently by the sense of impending change in national health programs. Any serious consideration of biomedical research policy must examine three related areas: the impact of such policies on health generally; their impact on the universes of science; and their impact on the institutions of higher learning, especially the medical and dental schools.

Let me focus on three issues which are still unresolved:

1. What is the nature of the decision-making process for a biomedical research program for the future?

2. What are the best mechanisms of support?

3. What should be the relationship with medical and other health educational schools?

There has been considerable discussion recently--both within the scientific community and in the halls of government--about the direction of research, The setting of priorities, the matter of "social relevance", and on how best to meet the needs of society.

Some have viewed this increased questioning of the substance and direction of scientific research by non-scientists as a call for more emphasis on targeted versus

fundamental research, on short term versus long term investment.

I believe on the contrary that these questions have a much more profound basis--that the public cares little how we weave our magic but only that we continue to do it. I believe society is quite as prepared as scientists to accept uncertainty where knowledge is lacking if they are so told. But many scientists--believing increasingly that only the short term, the immediate, has value in America--continue to promise unselectively that success is "just around the corner." The response often is, here's another $1 million, $10 million, or even $100 million to get us to the corner sooner.

Twenty-five years ago the problem in this country was to develop a national capability of excellence and effectiveness. That ambitious goal has been achieved so that today scientists and non-scientists see:

- The biomedical sciences seem uniquely ripe for vigorous exploration;
- We as a nation seem to be about to undergo major changes in our health delivery systems;
- Today the question is raised with increasing urgency. How do we arrive at decisions in the use of this biomedical research capability? How best to apply the great potential of dedicated scientists and resources in the health field to grave national

health problems?

I believe we should maintain a position of flexible diversity. We should not tie ourselves to one course of action.

To make this possible, we need a portfolio of mechanisms for supporting science in this country. We should maintain as a backbone of this portfolio our regular research grants, now constituting somewhat more than half of the total expenditures of NIH. They represent the clearest and most effective mechanism to focus our resources on the most creative scientists with the best ideas. They constitute a powerful monitoring and evaluative device. These grants are distributed after successive review by two nonfederal groups--the study sections and the councils. In addition, however, training grants, fellowships, institutional support mechanisms, center grants, contract funds, and intramural programs all have an appropriate place in our total national endeavor.

Because biomedical research depends on the colleges and universities of this land, NIH has always had close ties with the academic community, first through individual project grants and later through institutionally oriented grants. In recent years a new dimension was added to our relationship with health professional schools through our health

manpower responsibilities. This has come about at a time when financial crises are emerging in many of our nation's medical schools. The Carnegie Commission on Higher Education predicts similar problems in institutions of higher learning generally.

Here, too, we must maintain a kind of flexibility which will guarantee the independence and viability of the nation's colleges and universities, and at the same time help meet the national need for health manpower. The Administration's proposals in the health manpower field were designed with these purposes in mind.

The final issue I wish to pose is a question of priorities in the general allocation of resources. What is the place of biomedical research vis-a-vis the organization and delivery of health care and other national obligations? This issue is sharpened greatly by the contrast of rapidly escalating health costs at a time of severe budget constraints. Inevitably research has to compete with other national needs, both in health and in other areas of life.

Of great importance as this country seeks to provide a more rational health system for its people is the likelihood that biomedical research will be challenged as a less effective means of achieving that goal, at least in the

short-run, when compared with other means. At a time of major national change in the health field, it is inevitable that the question of the relevance of research will be raised. Answers must be given in terms of national need, not defense of the status quo. A convincing case can be made that health care in the future, as in the past, will depend primarily on the knowledge base from which it is practiced.

History provides not only striking evidence of the high social yield growing out of biomedical science, but also of how, in time of greatest stress, nations have recognized the importance of basic research. Lady Florey, with whose husband, Howard Florey, I worked almost 25 years ago, visited us recently, and we discussed the wisdom of war-time England's allowing the continuation of studies of natural antagonisms which led to a reexamination of Flemming's mold and the production of penicillin. This activity was continued in the face of possible invasion. Indeed, several members of the laboratory had the mold sewn in the lining of their clothes, so that if England were invaded, those who escaped would still be able to continue the work.

Florey's 100 percent fatality of untreated mice and 100 percent survival with penicillin required little explanation. The applicability of the results of much of today's research is not as clearcut. There are benefit-risk ratios inherent in many modern discoveries which must be evaluated. I need only mention the antidiabetic drugs and the oral contraceptives to make the point. The character of this issue suggests that the biomedical sciences of the future will offer not only the challenges of probing the basic life processes which I mentioned earlier, but will test severely our ability to make sound judgments in applying the results. The use of the results from the application of scientific experiments must increasingly be weighed against social, economic, political and behavioral beliefs and desires in the population. For this reason alone, the biomedical science frontier is more challenging and more demanding than it was 25 years ago.

I believe the science teachers of this nation, and programs such as the one we are celebrating tonight can help the American people recapture the spirit and the flavor of Dr. Bush's vision of an "endless frontier." With public support based on this kind of understanding, our future is

bounded only by our own creativity and will.

I would end by quoting three sentences from the Oxford History of America.

> "America was discovered accidentally by a great seaman who was looking for something else; when discovered it was not wanted; and most of the exploration for the next fifty years was done in the hope of getting through or around it. America was named after a man who discovered no part of the New World. History is like that, very chancy."

Since the nature of biomedical research is to provide the unknown, we should not be surprised that predictions about the future are also chancy.

Again, let me congratulate the award winners and express my appreciation that some of the group will be visiting the NIH reservation tomorrow. You will receive a warm welcome, I assure you, and I hope your exposure to our scientists and their investigations will serve to increase your already keen interest in a career in biomedical research--a career which, in my opinion, cannot be matched for its personal satisfaction and its contributions to the welfare of mankind.

TAB 14

#066

TRIP TO DENMARK AND LONDON RQM--ver 6/2/71

The purpose of the trip was to attend an invited conference called by the Danish Medical Research Council to include the Scandinavian Countries, Great Britain, the USSR, the USA and Japan. It was hoped that benefit would be obtained by comparison of the progress and problems shared by the various Medical Research Councils. It had appeared from preliminary conversations with Dr. Berliner, almost a year ago, and with subsequent correspondence that the Scandinavian Countries were especially hopeful, that this meeting would be helpful in itself and would establish a format for future communications. Indeed they had hoped that several people from each country could come, but a review of the purposes and Agenda, plus the heavy schedules, made it seem advisable for me to go alone. A second purpose of the visit was to respond to an invitation by Dr. Gray to spend the Whitsun holiday with him in Kingsand in Cornwall, and thus to have a chance to talk without interruption along the lines that had been so valuable last Fall.

I left on Monday, May 24, and had an uneventful trip until arrival in Copenhagen. There I found that my bag had been lost, probably because of the short time between flights in London in view of the large number of passengers carried in the 747. I did buy a plastic raincoat in view of the fact that it was raining, and although unable to change, was ready for the trip to dinner.

In keeping with the considerable emphasis that the Danes had put on this meeting, they had arranged that our first dinner should be held at the Prime Minister's summer home, and that it be hosted by the Chairman of the Scientific Committee of Parliament. A Senior Representative of the Ministry of Education was present, and expressed the regrets that the Minister of Education could not attend. We were told that neither the Russian nor the

International meeting of the Medical Res. Councils
Copenhagen, Denmark, May 25-28, 1971.

Japanese representatives were able to come, but that all other countries were represented, including John Gray, Secretary of the British Medical Research Council, and his Deputy, Griff Owen. We had an absolutely splendid and beautifully served dinner with an exceptionally good fish course, followed by duck.

The Chairman of the Science Committee welcomed us with a very warm speech, Professor Staudinger from Germany (which was also represented by Dr. Fisher) responded. We had a written speech delivered on behalf of the Minister of Education, and as I was sitting on the right of the host, I made brief comments. Following the meal proper, we moved into another room for dessert, and an opportunity to talk at some length. The main theme of the discussions that I had a part of were the problems of the small country, with a new Medical Research Council deciding best how to use its resources. On the one hand was the recognition that they could not cover all fields at the same time; on the other hand the example of the excellence of say a constituted strong incentive for serious support of individuals wherever their interests might lie.

I had a chance during the evening to talk to Kontorchef Jytte Kvorning who is, I believe, a lawyer, married to a physician, who carries a major staff responsibility for the Danish Council. She said just bringing together this meeting had consumed a great deal of staff time, and they were particularly well pleased to have such good representation from England, Germany and the U.S.A.

In addition, Dr. Martin Kaplan from the World Health Organization was a pleasant addition to the group. We went over the agenda a bit more,

particularly from the standpoint of the contribution that I might make, since it was clear that most of the people there knew science of the United States from the basis of personal visits. She advised that while that was true, few of them had actually been deeply involved in the administrative aspects, and that we were likely to make contributions which were greater than we might anticipate by focussing in a candid fashion on the problems in the allocation of resources as they had evolved in the States.

I also had the opportunity both during dinner and afterward to talk to a member of Parliament at some length. He appeared a strong advocate for biomedical research, was well informed and enthusiastic. He had been a teacher prior to running for the Parliament and is an historian by profession. He went into the political arena as an outgrowth of his interest in political history and eventually his desire to contribute to it. This was his first term.

I also talked to Professor Plum who had recently come on to the Council. He is a neurosurgeon, and was particularly interested in the application of science to the practice of medicine. All in all, this was one of the most delightful and well handled evening meetings I have attended for some time, although I gather the Danes were not quite as relaxed as they are traditionally thought to be.

The next morning I went over to a meeting with Dr. Kaplan, who is a virologist and who in addition, I believe, worked at one time with toxo-plasmoschisis, but I may be wrong. He has been at WHO for some years but periodically takes off time to go back to the Lab. He will be working with Hillary Koprowski on rabies vaccine for six months later this year.

We arrived at the Ministry of Education where it was suggested that we could not use slides because the rooms were old and could not be darkened. Thus it was necessary for me to make an "on the spot" modification in my presentation. We were asked as we had been requested in the correspondence to speak a few minutes on the organization and the functions of our various organizations. John Gray was in the chair. It was an informal meeting and we were in the following order: Denmark, USA, Germany, Sweden, Norway, Finland and England. It was proposed that we would spend the morning doing this with some time for discussion. It was announced by Dr. Siim that the representatives of the largest Medical Research Councils in the world had been invited, that the Japanese had said the distance was too great, and that the representatives of the USSR had said the invitation arrived too late. Dr. Siims made it clear that the invitation had arrived almost a year previously. However, I wondered if they did not address it to the wrong person--it went to Benedictus rather than to somebody in the Academy of Medical Science.

Dr. Povl Riis of Denmark pointed out that the Danish MRC has existed only since October 1968. He then described briefly and well the material which is included in a folder with a blue cover which had been sent to us previously. He struck an early note in differentiating between science strategy--which he called science policy--and science tactics--which he called science administration. He then went on to say that they still have the basic problem of determining how much of the nation's resources should go into medical research while in addition they are still evolving their administrative mechanisms for the distribution of such resources as are allocated for this purpose.

I will not spend much time talking about my presentation. I passed the

material around which had been prepared for the meeting which was well received. I organized my comments around the mission which is support of biomedical research, education in the health areas, and the National Library of Medicine. Then I said our activities are characterized by several relationships. First is the relationship of the Executive Branch to the Congress recognizing that at present these are controlled by different parties in our country; that Congress had dominated the development of NIH for a number of years, but that more recently this had moved toward the Executive Branch with a major change, however, in the 1971 budget. The second characteristic as far as relationships are concerned, is the government-nongovernment relationship. By this I meant the relationship with the universities on the one hand and with the peer review system on the other. Therefore it was well to distinguish between NIH, Bethesda, and NIH, USA. The third relationship was along categorical lines, and I recalled that the government practices followed in many instances the practices of the voluntary health agencies, and that the influence of such groups as the Heart Association, the Cancer Society and others with categorical activities at NIH was an important relationship. The fourth relationship which I organized my comments around was the absence of a fully evolved policy in our government as far as education, generally, medical education, specifically, and secondly health services, generally, were concerned. The rest of the comments I think were pretty general ones about the description of NIH, including the importance of the regular grants; the various mechanisms for shifting priorities, such as the establishment of new Institutes (for example the Eye Institute, the Heart <u>and Lung</u> Institute); the ability to

select scientific opportunities, such as dental or the genetic areas; the priorities which are established as the result of urgent social problems, such as environment, population, sickle cell anemia; and in the mixed group I talked briefly about cancer.

Dr. Fischer made the presentation for Germany, stating that in 1970 there was a budget of 318 million marks for science in total, of which 82 million was for biology and medicine. He then described as is outlined in the material which he provided us, the functions of the General Assembly, the Executive Committee, the Elected Committee which appears to be unique in that all of the scientists in West Germany can vote and can be elected. They ran into some problems in the definition of what a scientist is particularly in view of some of the student activities, so that basically now they define a scientist as being someone who is three years post-doctoral and is working in a scientific field. He admitted that even with this definition there are some problems.

Dr. Sandbo from Norway talked rather briefly about the Medical Research Council in Norway. It was mostly mechanistic, and I do not have notes on any outstanding feature.

Dr. Lamberg spoke for Finland and pointed out that their budget is approximately a half million dollars. They have focussed on the support of individuals, about 15 research professors, and they have a question now of whether they should be for life, or for say, five years. These are in addition to the professors in universities. There are fifty senior scholars, one hundred junior scholars and two hundred research assistants of which about half are working for Ph.D. I gather the other half are working for lesser

degrees. There are annual scholarships for about seventy-five qualified scientists at a salary level of a research professor. There are annual research grants which amount to about half of their total budget. They have special emphasis on cardiovascular diseases, particularly rheumatic diseases, also on arthritis and on neuropsychiatry. About half of their total budget is in these areas. There are, however, fifteen areas of special interest represented by special committees which are nominated by the MRC.

I will comment on Sweden later because I had a chance to talk to Dr. Gustafsson at dinner concerning the possibility of additional relationships with him.

Griff Owen talked about Great Britain. Sixty-five percent of their budget goes to seventy-seven institutes for intramural research, by our definition. They put a heavy emphasis on three-year project research but in addition have research programs for five years, renewable for one or two years. They also have contracts and some block grants. He commented on the autonomy of the Medical Research Council from the political process, pointing out that John Gray is the fourth Secretary of the MRC. He then commented on the three areas of the Medical Research Council in Great Britain--the Biological Research Board, the Clinical Research Board and in a smaller capacity, the Tropical Medicine Board. These are all scientific. He then described their method of having a scientific decision as far as the top projects are concerned, and as far as the bottom projects are concerned, but that the Medical Research Council itself decides on the basis of importance to the nation of the mid-group. They employ about 300 people, and generally are organized on a scientific basis, except for some grants

to universities, in the sense that they have units which have some freedom of action.

Dr. Kaplan, from the WHO, the Office of Science and Technology, reported on their activities. Their research budget at WHO is about $5 million a year, but he anticipates that this will increase to $8 or $10 million because of the new programs in population research. Dr. Kaplan outlined some of the advantages of working through WHO as being entree to various countries and resources which are not available to any one country, and mentioned geographic pathology as an example. He also pointed out that there are some WHO laboratories in addition to the $5 million he mentioned previously, such as special work in foot and mouth disease, and in some parasitic diseases. The $5 million is used as "   " and averages about $4,000 although a fair number are in the $1,000-$2,000 range for a piece of equipment or for facilitating cooperative work. There are 12,000 collaborating laboratories, including those that are primarily involved in standard work. They give as much freedom to the technical units as is possible. However, the activities are reviewed and run from Geneva. In addition they have about $225,000 for exchange of workers for up to three months, and they have 60 to 75 of these each year. They give some small grants to individual workers. The Office of Science and Technology is concerned with the application of science to public health problems. It is not operational as such.

We had lunch of very good fillet mignon, which was called a snack, and then returned to work. Dr. Gray started out by saying the proportion of public expenditures on research and development is now a significant

amount of the budget of all countries. Therefore the budgets will be looked at from many standpoints. Furthermore, many decisions will be made by a government which under idealized circumstances could be better made as the result of experiments, simply because there is not time to conduct the appropriate experiments. He commented that there are three parts or levels of scientific research--the pure research which is unrelated to any specific project; strategic research which is particularly important in coordinating the work of medical research councils with other scientific research councils; then there is the research to produce specific answers to specific questions, including surveillance. During the discussion, and in the earlier discussion of Norway, it was pointed out that originally the research funds had come from the football pool, almost as if research were an after-thought, but that now with the increase in importance of biomedical research there was a separate budget. This brought up the question of the importance of biomedical research vis a vis national needs, and the fact that sometimes the experimental approach is asked to answer serious questions which have not lent themselves to solutions as the result of broad economic changes or political changes. In other words, because of frustrations of other approaches sometimes more is expected of the experimental approach than one indeed should expect realistically.

All in all, the discussion on Wednesday afternoon pointed out repeatedly the basic dilemma of increased urgency on the part of government in the political sense to find practical answers and the fact that this pressure was frustrating those most knowledgeable in the scientific fields. At one point there was a discussion about the possible need almost to give up on the possibility of truly educating populations in general to the

potentials and limitations of the scientific approach, but to promise them practical results and use the funds so generated to further advances in science. I recounted the major pitfalls that the United States had already encountered by a perception of over-promise, and there was general agreement that one had to be absolutely candid and honest, even if in the short-term this worked to the detriment as far as generation of funds was concerned.

The Scandinavian countries were particularly interested in the precise mechanism for allocation of funds for projects, and I was quizzed in some detail about our review mechanisms as was Dr. Gray, so that a fair amount of time was spent on descriptive discussions. However, underlying all of this was the theme of the previous evening of how can small countries faced with the impossibility of covering all areas of biomedical science choose wisely which areas to develop, or alternatively, find some way to develop cooperative efforts.

It is difficult to evaluate the value of this day of discussion from the standpoint of the United States. There were repeated references that no country except perhaps the United States could have a comprehensive program and yet as I listened to the issues being discussed, it seemed to me that the same type of impatience was being experienced in the small country as in the large for the promise and delivery of solutions to the broad and complex social problems being demanded of the research endeavors in the countries represented. Despite the considerable enthusiasm for the progress and promise in biomedical research no one in the group felt that the extravagant demands being hoped for by our societies would in fact be met on anything like the timetable hoped for. There was repeated concern about the possibility of over-promise, the inadvertent deception, and well-intended but serious

meddling with the scientific endeavors of nations. Although these coincided with my own biases and concerns, I was somewhat surprised to see them stated so strongly by socialist and near-socialist nations. As an aside, it seemed clear that none of the nations represented felt very comfortable that the problems of the organization and delivery of health services had indeed been solved.

Following the meeting, Dr. Gray, Dr. Gustafsson from Sweden and I had dinner together, since Dr. Gustafsson wanted to talk to both of us. We spoke specifically about the need for additional agreements between Sweden and the United States, and it was my clear understanding that he was not seeking any such arrangements at this time, but felt that in general the relationships on a scientist-to-scientist basis were serving their needs very well. He did ask specifically if we might be able to review a grant which they are prepared to turn down, but would like to get an outside opinion. I suggested that he could follow either of two courses--to have the applicant submit an application to NIH, in which case it would go through our normal review mechanisms, or alternatively he could write me directly and I could see what we could do to help. It turned out that I had known of his work back from the earlier years when he was one of the few people in the world carrying out the germ-free animal experiments, and he had known of my work at the same time, in whole-body radiation and the role of infections. I would want to talk to Dr. Leavitt about my discussion with him, but my perception from this brief encounter was that he was not at all interested in any additional arrangements other than those that we have at present. He commented favorable on his contacts with Marty Cummings

and Ken Endicott (despite the absence of any fish on their last trip), and was most willing to be responsive should there be areas of joint activities which should be undertaken. He did in fact feel that I should visit Sweden sometime in the future, but whether this was hospitality or science, I am not sure. Dr. Gustafsson had to leave to go back to Sweden, so after dinner (which incidentally was fried eel) we walked through the Tivolli--a large multi-faceted park in the center of the city--hoping to stay up for the fireworks at 11:00 o'clock, but both of us folded before that time.

The next morning, Thursday, started at 9:00 a.m. and there was first a discussion of the need to exchange information among the Medical Research Councils. It was recognized that the suggestion to send all reports to each other raised special problems for Great Britain and NIH in view of the great bulk of materials produced. Dr. Siim however is particularly anxious to get what I gather was our summary to the Secretary prepared by Bob Berliner which I believe we have discontinued. We should do a screen to see which productions would be most useful. (June 4 letter to Dr. Siim confirms we will send our weekly report on research highlights to him, pointing out distribution is limited to internal use and he should treat it in like fashion.)

The second area was the question of exchange of fellows, and here the discussion varied from the WHO "country" allocations to the one-to-three month fellowships which have been mentioned previously. In the midst of that discussion there was a request that we improve our mechanisms of letting applicants for grants or fellowships know either yes or no promptly. The other MRC's have no complaint if an applicant has been told that he will

not in fact be supported by the NIH, but if they are lead to believe they might be supported and then find out that they will not be, the MRC's are under pressure to pay out of limited funds. I pointed out that this had been a problem in the States due to the uncertainty and the lateness of appropriations, but we were aware of the problem on the domestic level and could in fact take corrective action. There was considerable discussion of the value of the NIH post-doctoral fellowships, and once again I feel that we must re-examine the value of these fellowships from every aspect--the science point, the public relations aspect in the international field, and the great value fellowships serve in directing some of the best young minds to our country's problems. Even with the modesty characteristic of this group it was clear that these funds had served a major purpose far beyond their dollar value.

There was again the discussion of the difficulty of choosing fields in which to put priorities, of the question of the support of individuals versus the dependence on directed research and of the need for international cooperation. Under the latter, Dr. Kaplan made a strong plea for support of the WHO population studies. I felt compelled to point out some of the problems in looking to research as a possible solution of the population problem. Gray supported my position, but I gather that the World Health Organization has again through frustration about other mechanisms for handling the population problem decided that research is a good, safe bet. In addition, I get the clear impression that now that the U.S. Government is putting more funds into population research private sources such as the Ford Foundation are prepared to use funds freed by the government entree into a higher level into this field on the WHO level. There was a rather strong

plea from a dentist in the Danish group to consider dental caries as the type of research problem that lent itself to WHO coordination. He also included here peridontal disease as probably an infectious process similar to dental caries which also might be included. He named incidentally that Scandinavia, Switzerland, NIH and the United Kingdom probably constituted the World's resources as far as activities are concerned in the dental area.

Dr. Riis made a very cogent comment on the need to further person-to-person relationships across International boundaries. Dr. Kaplan came back to the advantages of WHO in providing entree and in providing ideas which are in fields that may be limited in any one country. He also pointed out the need for primate facilities. Along these lines Dr. Gray said that for the long range, he believed in fact there should be a situation in which people can move from country to country as easily as they move from Boston to San Francisco, but that the actual working out of such a system is very difficult.

We broke for lunch at a delightful old Inn and visited the Viking Ships. This provided an excellent opportunity for informal discussions and emphasized the much closer relationship of people in Europe generally to the States than is true vice versa. For instance, Dr. Siims has a daughter living in Silver Spring who may in fact get in touch with me. Griff Owen, from England, is married to an American who has relatives in Philadelphia and may be coming over this summer. Dr. Kaplan, of course, will be in Philadelphia. As I commented earlier most of the others have at one time or another spent some time in the States. Far more than any other country, and probably in any other field the United States is looked

to as the leader in the area of biomedical research. However, the situation has changed markedly from a few years ago when it was looked to as almost the sole source for financial support, and even the smaller countries now are quite willing to pay their own way, but with no complaint for instance, about the dropping off of grants. I would add that I got the impression while in Canada as well as at this meeting, that the withdrawal of NIH overseas funding which was so valuable at a crucial time in the support of science in these areas is now afforded from indigenous sources. Hence there is no need to return to the previous system of NIH grants assistance. However, since for several years the NIH did dominate the dollar support for biomedical research around the world, it also played a coordinating role, and a void has now occurred. Now that individual countries have in fact taken up the slack resulting from a decrease in the dollar support from us a void has occurred in terms of coordination, and there is an active seeking of some mechanism to fill this void. While we were still in Denmark and also later in England, it was possible in talking with John Gray to focus somewhat on this need. I suspect that the next meeting of this particular group may well be around the European common market and potentially common market countries and one might see a regionalization on a world-wide basis of coordination.

Among the various problems that one has is the discrepancy between the biomedical research activities of the advanced nations and the developing nations. I feel more as a result of this meeting than I have previously that we at NIH should give some fairly serious consideration to the problem of a meaningful international biomedical research interchange although at

this meeting as well as at previous meetings there is a strong suspicion that if these must go through all of the problems of formal nation-to-nation agreements that they will be doomed to failure.

Much of the discussion of the afternoon was on the various attempts to bring the European community together. Molecular biology activities stimulated a spirited discussion, in part characterized by the special pleading of a group of scientists on the one hand, and the realization in the countries represented that there is unlikely to be any additional funds available so that international activities must in fact compete with national endeavors. It was pointed out that the physicists made a clear decision in Great Britain to close down some of their labs in order to create a physical facility of a cooperative nature.

After the trip to the Viking Ships with a description of the ships that had been dug up in the harbor where they had been sunk for a thousand years as a defense protection in the channel, we returned and the foreign visitors--that is the non-Scandinavian visitors--went to a very, very excellent performance of the Royal Danish Ballet Company. Following that the two Germans went to eat (since Dr. Fischer's wife was present and they had not dined) while Kaplan, Gray, Owen and I went back to the hotel and spent about forty-five minutes of interesting conversation about the role of international cooperation. It will be worthwhile for me to drop a note to Kaplan to ask him to come down and talk to us I think sometime during his time in Philadelphia.

We were off early Friday morning, made the trip to England, caught the train and arrived late evening at Kingsand. John's wife and children

had to work and so he and I had a delicious lobster after a brief stop at one of the local pubs. This was perhaps the best evening for discussions. I will not try to cover all the things that are happening at the MRC at present, first because a fair number of them are still confidential and we will receive some papers later, and secondly because Carl has just recently completed his month and will be able to provide a much fuller account of what is happening. Suffice it to say that the problems that were emerging with the Agriculture Research Council last fall have not improved. After more than fifty years the firm public policy in Great Britain to separate the Research Councils from political influence is being questioned, and in at least several of the Councils is being reexamined to the serious concern of many. There are repeated assurances that the Medical Research Council will not in fact be included in the potential movement of all or parts of the other Research Councils to become parts of Government, but in fact there is serious concern. While the difference in magnitude of political interference in scientific affairs should be noted, the fact that it is indeed occurring in Great Britain at this time, is more surprising than that it occurs in our Country. The Agricultural Council is one example; Heath's letter to Nixon on the cancer research activities is another. I would not want to exaggerate the concern in Great Britain, but it is very clearly there.

Vera, Peter and Clair arrived at 3:00 a.m. in the morning, after a very long and difficult trip in view of the Whitsun traffic. Saturday was cloudy with some rain early in the morning, but by the time that all of us were up the skies were clearing and we took a beautiful sail in John's boat

up the Yam which is around the mew rock where we anchored and had tea and then had a delightful sail back.

A brief word about the children. Peter is working as a biochemical technician, incidentally partially supported apparently by NIH funds. He enters Cambridge this fall in the natural sciences, and since Ann and I saw him briefly he has grown a full beard and another couple of inches of hair. This summer he is off with friends in a land rover bought from a man who bought it from the Queen, or at least from the Queen's estate. Clair was to have been married this summer to her fiance named Ted, but he if off to Brazil in the British foreign service, and there is some question of whether she is in fact engaged at this time. She is finishing her masters in what would probably be best described as ecological conservation, and during the next week will make critical decisions concerning a job for the next year.

On Sunday the weather was even better than Saturday, and we sailed in the opposite direction--I guess the course taken by the Pilgrims as they left for America--and went around Ramshead with a beautiful brisk breeze. We had crab, and then on Monday having the best weather of all we sailed up the river past the Naval vessels. Since Clair and Peter had to go back to London we left Vera and them off, and John and I went out for sixteen knots' wind sail out into the Atlantic Ocean in the sparkling sunshine and came racing back some seven or eight miles with full red and white spinnaker. I took them to dinner at a local pub and we all collapsed after a very full day.

John took me to the train. I made an uneventful trip to London where the plane was an hour late which gave me a little time to do some shopping.

BACKGROUND INFORMATION ON THE ORGANIZATION AND BUDGET OF THE NATIONAL INSTITUTES OF HEALTH[1]

Robert Q. Marston, M.D.[2]

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[1]Prepared for International Meeting of the Medical Research Councils, Copenhagen, Denmark, May 25-28, 1971.

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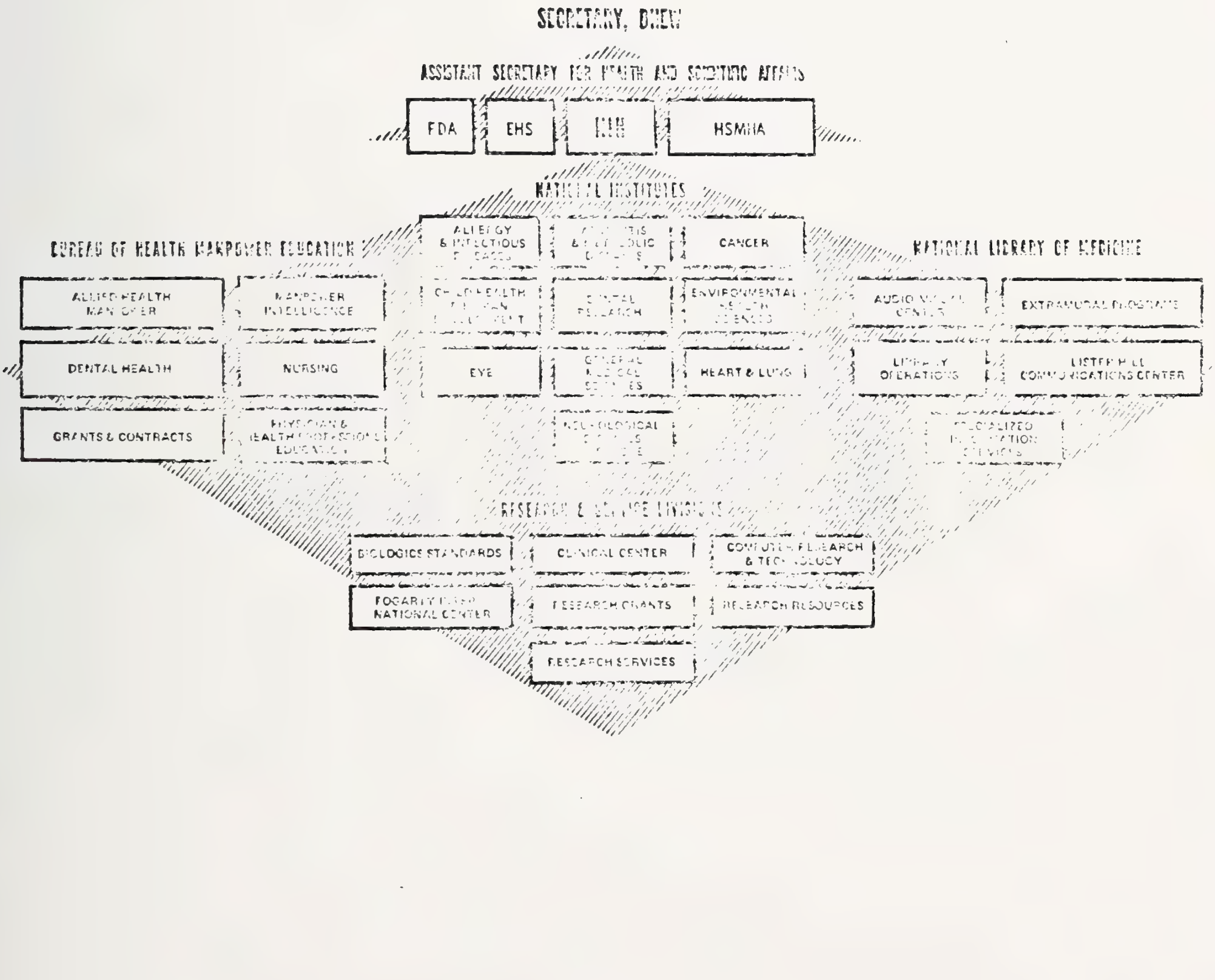
I. ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH



Principal Officers, National Institutes of Health:

Director	Dr. Robert Q. Marston
Deputy Director	Dr. John F. Sherman
Deputy Director for Science	Dr. Robert W. Berliner
Director, Bureau of Health Manpower Education	Dr. Kenneth M. Endicott
Director, National Library of Medicine	Dr. Martin M. Cummings
Associate Director for Health Manpower	Dr. Leonard D. Fenninger
Associate Director for Program Planning and Evaluation	Dr. Thomas J. Kennedy, Jr.
Associate Director for Administration	Mr. Richard L. Seggel
Associate Director for Communications	Mr. Storm Whaley
Associate Director for Clinical Care	Dr. Thomas C. Chalmers
Associate Director for Extramural Research and Training	Dr. Ronald W. Lamont-Havers
Assistant Director for Collaborative Research	Dr. Leon Jacobs

II. THE CURRENT YEAR (FISCAL YEAR 1971) BUDGET

A. Chronological Development

For the first seven months of this fiscal year, NIH, like other agencies of the DHEW, operated under the provisions of a continuing resolution of Congress, which restricted operations to last year's level. However, the fiscal year 1971 appropriations bill, which provides substantial increases in funds for NIH, was passed by Congress and approved by the President on January 11, 1971. Thus, these substantial increases for NIH are, in a practical sense, available for use in no more than five months during the current fiscal year. Following is a table which shows the progression of the current year budget (in terms of pluses and minuses) in comparison to last year's budget.

(In thousands)

Activity	F.Y. 1970 Actual	Fiscal Year 1971 Changes Over 1970: President's Budget	Congr. Approp.	1971 Column of 1972 Budget*
Institutes & Research Divisions				
Research grants..............	$592,689	+$15,030	+$79,821	+$74,103
Training grants & fellowships	155,971**	-1,732	+10,730	+3,289
Collab. res.(mostly contracts)	127,083	+43,072	+58,384	+55,905
Intramural research..........	90,302	+9,539	+13,401	+15,598
Other direct operations......	46,471	+2,850	+3,423	+4,843
Subtotal, IRD's...........	1,012,521	+68,759	+165,759	+153,738
Bureau of Health Manpower Educ.				
Medical, dental and related health professions.........	301,204**	-1,883	+35,877	+22,377
Nursing......................	50,259	+15,249	+24,749	+23,249
Public health................	17,970	-969	+531	+531
Allied health................	13,407	+6,080	+6,080	+6,080
Prog. dir. & manpower anal...	5,020	+252	+252	+252
Other........................	13,515	-10,432	-10,432	-10,432
Subtotal, BHME............	401,375	+8,297	+57,057	+42,057
National Library of Medicine...	19,979	+302	+1,302	+1,531
Other..........................	10,058	+7,307	+7,307	+7,543
Total, NIH.............	1,443,933	+84,665	+231,425	+204,869

*Reflects pay increases.

**Reflects comparative transfer of $23,000,000 for the salary components of research training grants in health professions schools from the Institutes to the Bureau of Health Manpower Education.

B. Explanation

1. The President's 1971 budget, submitted a year ago, provided for the following:

a. An increase over fiscal year 1970 of $68.8 million for research or about 6 percent, reflecting:

(1) Significant increases for cancer ($22.6), family planning and population research ($12.8), early childhood development ($6.5), heart and lung diseases ($13.0), and dental research ($5.9);

(2) A hold-the-line policy on research training grants, pending the outcome of a study of this program; and

(3) A 20 percent decrease ($10.5) in general research support grants.

b. A net increase of $8.3 million for health manpower education, reflecting:

(1) Increases of $22.2 million for grant support to schools of medicine, dentistry and osteopathy, schools of nursing, and institutions providing allied health training;

(2) A decrease of $3.5 million for student assistance based on the assumption that scholarships and direct loans should go for the most part to students from families with incomes below $10,000 and that students from higher income families should take advantage of the loan guarantee program of the Office of Education; and a decrease of $0.6 million in public health traineeships.

(3) A decrease of $3.1 million for the elimination of basic improvement (formula) grants to schools of veterinary medicine and reductions in grants for graduate public health training; and

(4) A reduction of $23 million in total obligational authority for construction grants to health professions schools and the anticipation that support of construction of teaching hospitals would be shifted to a loan guarantee method of financing (with Federal subsidy) through the Hill-Burton program.

c. Maintenance of the National Library of Medicine's programs at approximately the previous year's level.

2. Congressional action on the appropriation bill, as compared to the President's budget, provided for the following:

a. A further increase of $97.0 million for research, reflecting:

(1) Increases above the President's budget for cancer ($28.0 million), heart and lung diseases ($21.7 million), stroke in the National Institute of Neurology and Stroke ($8.8 million), and genetics in the National Institute for General Medical Sciences ($10 million); and

(2) Across-the-board "cost of living" increases of $38.5 million designed to bring research activities, including the research training programs and the general research support grant programs, up to the 1970 "program level."

b. Increases for the Bureau of Health Manpower Education of $48.8 million, including:

	(Millions)
Medical, dental and related institutional support (including restoration of $2.7 million for base grant support of schools of veterinary medicine)	$10.7
Nursing institutional support	0.5
Public health training programs	1.5
Medical, dental and related scholarships	0.5
Medical, dental and related student loans	13.0
Nursing student loans	7.5
Construction--of which $1.5 million was for nursing school construction; the remainder for medical, dental and other health professions schools	15.0
Division of Dental Health research grants	0.1

c. A $1.0 million increase in the National Library of Medicine, with $0.5 million for the Lister Hill National Center for Biomedical Communications and $0.5 million spread among the other Library programs.

3. <u>The amounts of the fiscal year 1971 appropriations which will be made available</u> through the apportionment process reflects the utilization of the following to cover the deficiency which resulted from increased pay costs. (All funds were used within NIH except $1.9 million transferred to St. Elizabeths Hospital):

a. Congressional increases of $7.5 million for research training grants ($0.8 million of the $7.5 million in the Cancer and Heart appropriations will be reprogrammed for purposes other than pay raise or training); this reflects the hold-the-line policy pending the outcome of the study.

b. $6.5 million of the Congressional increase of $12.9 million for general research support grants ($1.9 million in the Cancer and Heart appropriations to be reprogrammed within these appropriations for uses other than pay increases).

c. $2.25 million from the $10 million Congressional increase for genetics and $2.25 million from the Congressional increase for stroke.

(Note: The use of $15 million Congressional increase for construction grants to medical, dental and other schools will be deferred to fiscal year 1972.)

Activity	1971 Column Comparable (In thousands)	1972 Estimate (In thousands)	Change (In thousands)
Institutes and Research Divisions			
Research grants.....................	$666,792	$685,341	+$18,549
Training grants and fellowships.....	159,260*	152,239*	-7,021
Collaborative res.(mostly contracts)	182,993	186,758	+3,765
Intramural research................	105,900	113,394	+7,494
Other direct operations............	51,314	54,109	+2,795
Special cancer initiatives.........	....	100,000	+100,000
Subtotal, IRD's..................	1,166,259	1,291,841	+125,582
Bureau of Health Manpower Education			
Medical, dental and related health professions...............	323,581	434,045	+110,464
Nursing............................	73,508	67,000	-6,508
Public health......................	18,501	18,544	+43
Allied health......................	19,487	30,654	+11,167
Program direction & manpower anal...	5,272	6,682	+1,410
Other..............................	3,083	4,000	+917
Subtotal, BHME...................	443,432	560,925	+117,493
National Library of Medicine.........	21,510	21,981	+471
Other................................	17,601	18,423	+822
Total, NIH......................	1,648,802	1,893,170	+244,368

*Reflects a comparative transfer in each year of $23,000,000 from the Institutes to the Bureau of Health Manpower Education for the salary components of research training grants awarded to health professions schools.

Highlights of the 1972 Budget

The President's 1972 budget for NIH provides an overall increase of over $244 million, or 15 percent, over fiscal year 1971 and $449.2 million, or 31 percent, over fiscal year 1970.

1. Research: The requested net increase for research over fiscal year 1971 is $126 million, or 11 percent. Compared to fiscal year 1970, which is essentially the level at which NIH has been operating for the first seven months of the current fiscal year, the budget increase for research totals $279 million and amounts to an increase of 28 percent. The major features of the budget for research are:

a. An increase over fiscal year 1971 of $100 million for a special, targeted attack on cancer, which is in addition to a $50 million increase provided in the current year for the research activities of the National Cancer Institute (the major aspects of the $100 million new initiative were presented in the President's Health message); the present plans provide for the use of $25 million of these funds beginning this fiscal year through the mechanism of advance obligational authority; in this manner, launching of the attack may begin prior to passage of the 1972 appropriation;

b. An increase of $5 million for research in sickle cell anemia to be funded through the National Heart and Lung Institute (Note the NHLI budget in fiscal year 1971 contains an increase of $34 million over fiscal year 1970, mainly for arteriosclerosis and lung research);

c. Increases in other special initiative areas, including over $9 million for family planning research, $5 million for environmental health sciences, and $3 million for dental caries research;

d. Increases of $23 million for non-competing continuation research grants ("moral commitments");

e. Decreases totaling $41.6 million in other research areas considered to be of lesser priority--e.g., general research support grants, artificial heart and kidney programs, perinatal studies, drug coronary study, regular research grants and intramural research in non-initiative areas, and fellowships; and

f. A shift of $23 million attributable to the health professions school salary components of the research training grants programs of the several Institutes to the Bureau of Health Manpower Education; the objective is to support the current level of research training pending the outcome of the training study (now scheduled for completion in September 1971) but to do so in such a way as to put more flexible means of control in the hands of the school Deans.

2. Health manpower education: The President's 1972 budget provides a total increase of approximately $117 million over 1971 and $150 million over the 1970 level for health manpower education. The major features are:

a. A net increase over fiscal year 1971 of $114.5 million for support to medical, dental and related health professions schools, reflecting:

(1) A $113.0 million increase for institutional support*
(2) A $6.25 million decrease for direct loans to students
(3) A $13.4 million increase for scholarships
(4) A $1 million increase for dental programs, including fluoridation and training in the use of dental auxiliary personnel

b. A net decrease of $6.5 million for schools of nursing consisting of:

(1) A $7.5 million decrease in direct loans to students
(2) A $1.0 million increase in training of teachers, supervisors and administrators
(3) A $1.0 million increase for nurse refresher training
(4) A $0.5 million increase for supporting activities

(The fiscal year 1971 budget shows a net increase of $23.2 million for nursing over fiscal year 1970.)

c. A net increase of $11.2 million in the allied health programs, reflecting:

(1) An increase in institutional support of $0.25 million
(2) An increase of $10.25 million in special projects for experimentation, demonstration, and institutional improvement related to training or retraining of allied health personnel
(3) An increase of $0.5 million for staffing regional offices

d. A $16.0 million decrease in construction assistance to health professions and nursing schools

3. <u>National Library of Medicine</u>: This appropriation is being maintained at about the 1971 level (which reflects a $1 million increase over 1970).

*This is in addition to the $23 million transfer of research training funds from the Institutes, which is reflected in the budget "base" of the Bureau of Health Manpower Education (i.e., in the 1970 and 1971 columns as well as the 1972 estimate).

IV. FEDERAL BUDGETS FOR MEDICAL R&D, FY 1970-1972
(in millions)

Agency	1970 actual	1971 est. obligations	1972 est. obligations	increase 1972/71	Percent increase
Total	$1,664	$1,933	$2,087	$154	8
VA	59	62	62	-	0
DoD	125	117	122	5	4
AEC	104	105	104	-1	-1
NASA	86	103	78	-25	-24
NSF 1/	28	30	32	2	7
DHEW	1,177	1,324	1,438	114	9
(NIH)	(873)	(1,039)	(1,168)	(129)	(12)
Agriculture	50	55	56	1	2
Environmental Protection Agency	-	85	100	15	18
Other	35	52	95	43	83

1/ For FY 1971 and FY 1972, excludes those research programs transferred to the Environmental Protection Agency, December 1970

Note: Covers support of medical and health-related R&D (projects, resources, and general support including PL 480 funding for research) but not training or construction

V. LEGISLATION AND PENDING BILLS AFFECTING NIH'S ORGANIZATION

Health Manpower Legislation

Health Professions Educational Assistance

There are three major proposals so far, offered by the Administration, the Association of American Medical Colleges and the Federation of Schools of the Health Professions, and Representative Paul Rogers (D-Fla.).

The Administration proposal (H.R. 5614, Staggers; H.R. 5767, Nelsen and others; and S. 1183, Javits) would provide for capitation grants of $6,000 per graduate for schools of medicine, osteopathy, and dentistry, with adjustments for student transfers and shortened curricula. It would provide separate authorities for special project grants to schools of medicine, osteopathy, and dentistry; schools of pharmacy, optometry, podiatry, and veterinary medicine; and schools in financial distress. Added are authorities for grants to aid disadvantaged students and to improve area or specialty distribution of manpower and for traineeships in medicine, osteopathy, and dentistry.

A new authority for Health Manpower Education Initiative Awards would permit grants for a variety of purposes, including establishment of area health education centers, training for better health care delivery in the context of the team approach and health maintenance organizations, and the like.

A consolidated construction authority (manpower, medical libraries, and health research) is provided, including authority to make grants (up to 67%), and guarantee loans, and pay up to 3% interest subsidies in the case of private sponsors.

The loan ceiling for health professions students is increased from $1,500 to $5,000 annually under the Higher Education Act of 1965. The bill liberalizes repayment terms and includes Federal repayment of loans to students who practice in health manpower shortage areas or certain specialties in short supply. Also forgiven are loans to students of medicine, osteopathy, dentistry, or nursing who are from low-income or disadvantaged families and who fail to complete their health studies.

The existing scholarship programs for health professions students, which are due to expire at the end of the current fiscal year, are extended for three years. The bill also makes discretionary the present mandatory program of grants for scholarship aid to schools of optometry, podiatry, pharmacy, or veterinary medicine, but continues grants to schools of medicine, osteopathy, and dentistry on the present mandatory footing. It increases maximum health professions scholarships from $2,500 to $3,000 and limits scholarships to exceptionally needy students from low-income or disadvantaged families.

The bill authorizes appropriation of such sums as necessary for the above purposes.

The AAMC proposal (H.R. 4171, Staggers; S. 934, Kennedy) would also provide capitation grants, at the level of $5,000 per student for schools of medicine, osteopathy, and dentistry; $3,500 for optometry, podiatry, and veterinary medicine, and $2,000 for pharmacy. It raises the schools' base grant from $25,000 to $50,000 and authorizes such sums as necessary for formula support. Special project grant authorization for 1972 is $150 million.

The bill would extend existing construction authority for five years, authorizing $300 million for 1972. It would raise the student loan ceiling to $3,500 per year and extend forgiveness provisions to all HPEA professions. It raises the maximum annual amount of scholarships from $2,500 to $3,500 and increases the allotment factor from $2,000 to $3,000 times 10% of enrollment.

A second AAMC proposal (H.R. 4170, Staggers; S. 935, Kennedy) would authorize grants for start-up, construction, and initial operating costs for new or significantly expanded schools of medicine or osteopathy; grants to assist academic health centers in planning and initiating health maintenance organizations; and grants to assist in the establishment of area health education centers.

The Rogers proposal (H.R. 4155) eliminates the base grant to schools and substitutes a $3,500 capitation formula for all enrolled HPEA students. Special project authorization is $105 million for 1972.

Construction authorities (other than health research facilities) are extended for three years, with a 1972 authorization of $325 million. The health research facilities authority is replaced by a new graduate training grant authority for which $10 million is authorized in 1972.

The Rogers student aid proposal is essentially similar to that of the AAMC, except that forgiveness of any educational loan is provided for physicians, dentists, or podiatrists who contract to practice three years in a shortage area.

Nursing

There are two major proposals: the Administration bill (H.R. 5614, above) and Representative Rogers' bill (H.R. 4618). Other bills have been introduced but were not available at this writing.

The Administration bill deletes the authority for construction of nurse training facilities (it is included in the proposed new consolidated construction authority). It would not extend the authority for formula grants but would extend special project grants for three years, adding specific authority to train, or develop training for, new levels or types of nursing or related skills, and to promote full utilization of nursing skills.

It would extend for three years the program of advanced traineeships for professional nurses, and authorize such sums as necessary for such purposes. It would broaden the authority for contracts and grants to identify potential nursing candidates and encourage them to undertake nurse training or retraining.

The Rogers bill (H.R. 4618) would continue the formula grant authority with a grant of $2,000 per full-time enrolled student and would authorize $20 million in special project grants for 1972. It authorizes $40 million in construction grants for 1972.

It would continue the traineeship authority, raise the student loan ceiling from $1,500 to $2,500, and allow forgiveness of up to 100%. The allotment formula for scholarships is increased from $2,000 to $3,000 times enrollment.

House hearings were held in April and the Subcommittee on Public Health and Environment is expected to present its marked-up proposals in the near future to the full Interstate and Foreign Commerce Committee. The Senate Labor and Public Welfare Subcommittee on Health held three days of hearings in early May. No decision has been reached on further hearings or a mark-up date.

Other Pending Bills

Proposed National Cancer Authority

The Chairmen of both the House and Senate Committees having jurisdiction over health legislation introduced bills in December 1970 [S. 4564 (25 co-sponsors), H.R. 19966, and four other House bills] calling for a transfer of employees, contracts, property, and resources from the NCI to the National Cancer Authority. The NCI and National Cancer Advisory Council would "lapse."

On January 26, 1971, Senator Kennedy, new Chairman of the Senate Health Subcommittee, introduced S. 34, the "Conquest of Cancer Act," which would also transfer NCI's functions to a National Cancer Authority. The bill now has 52 co-sponsors. Twelve similar bills with more than 100 co-sponsors were introduced in the House. Hearings were held on S. 34 on March 9 and 10, 1971.

The Senate Labor and Public Welfare Subcommittee on Health was scheduled to mark up S. 34 on May 11, but postponed action to allow consideration of the Administration proposal, introduced as S. 1828 by Senator Dominick (R-Colo.), as H.R. 8343 by Representatives Staggers (D-W. Va.) and Springer (R-Ill.), and as H.R. 8364 by Chairman Rogers (D-Fla.) and a bipartisan group of eight members of his Subcommittee on Public Health and Environment.

The President's proposal calls for establishment of a Cancer-Cure Program in the National Institutes of Health, reporting to the President, who could delegate certain functions to the Secretary of Health, Education, and Welfare. Another significant development in the Administration program is that the extra $100 million for cancer research announced by the President in his February Health Message is being requested as part of a 1971 supplemental appropriation. If approved by Congress, those funds would become available on July 1, 1971, eliminating the delay anticipated from late enactment of the 1972 appropriation.

Also pending are five amendments to S. 34 sponsored by Senator Harrison A. Williams (D-N.J.). The purpose of these amendments is to answer criticism that enactment of S. 34 would disrupt biomedical research. They would provide for coordination with the NIH and peer review.

The Subcommittee will hear a panel discuss the pros and cons of the above proposals during the first week in June.

Proposed National Kidney Disease Act

Forty members of the Senate and 113 members of the House co-sponsored identical bills in the 91st Congress (S. 2482, H.R. 12425, and others) to amend the PHS Act by adding a new title, "Title X--Education, Research Training, and Demonstrations in the Field of Kidney Disease."

No hearings were held on these bills. Although the scope of RMP has been expanded to include kidney and other related diseases (P.L. 91-515, October 1970), no research functions are being transferred from the NIH.

However, six new bills similar to those proposed in the last Congress have already been introduced thus far in the 92nd Congress.

New Institute Proposals

The Second Session of the 91st Congress featured a slackening of the brisk pace at which legislators introduced bills to establish new institutes at the NIH. None of the proposals advanced far in the Congressional process. However, the 92nd Congress has already generated a number of bills directly affecting NIH functions.

National Kidney Institute
- H.R. 497 - Whalley, 1/25/71

National Institute of Marine Medicine and Pharmacology
- H.R. 547 - Downing, 1/25/71

National Institute of Digestive Diseases and Nutrition
- S. 305 - Kennedy, 1/26/71
- H.R. 3665 - Staggers, 2/4/71
- H.R. 4837 - Hanna, 2/23/71

National Institute of Gerontology
- H.R. 188 - Jacobs, 1/22/71
- S. 887 - Eagleton, 2/19/71
- H.R. 4979 - Jarman, 2/25/71
- H.R. 6405 - Thone, 3/18/71

National Sickle Cell Anemia Institute
- H.R. 7654 - Grasso, 4/22/71
- H.R. 8423 - Hicks, 5/17/71

Enacted Legislation

Occupational Safety and Health Act of 1970

This broad legislation which was recently signed into law (P.L. 91-596) provides for promulgation and enforcement of standards, largely through the Department of Labor. It also provides, for the first time, a specific statutory basis for DHEW's activities in the field of occupational health and safety.

The Director of the National Institute of Occupational Safety and Health will have authority for the study of specific diseases within the dimensions of the occupational environment, although, in a general sense, responsibility for the study of these diseases is already vested in the various Institutes within the NIH (particularly the NIEHS), as well as in other HEW agencies. For instance, laboratory studies on chronic low-level exposure in the occupational environment are virtually identical with those in the general population. Another example is the problem of pulmonary diseases in the occupational environment (NIOSH) versus the general environment (NIEHS and NHLI).

TAB 15

ENVIRONMENT FOR PROGRESS IN SCIENCE*

Robert Q. Marston, M.D.**

There are a number of reasons that I am pleased to be with you today, but I shall mention only three. The first is to use the two events that we are here to celebrate--the dedication of the W. Alton Jones Cell Science Center and the 25th Anniversary of the Tissue Culture Association--to examine some of the environmental conditions which must be satisfied if progress is to be made in science. Second, I wish to express my personal congratulations to you on the achievements associated with today's events.

It was in fact only three years after the founding of the Tissue Culture Association that I became involved with the group. Later I took the Tissue Culture course at Cooperstown, conducted by Charles Pomerat and John Paul, and naturally became a member of the Tissue Culture Association, as one who was impressed with its dedication to keeping the dues low and the membership requirement restricted only to those interested in tissue culture.

My third reason is also personal, because this is the first meeting of the Association without George Gey being here in person. This giant in the field of tissue culture influenced the Marston family from the time that the wife of a busy intern became his first full-time secretary, and through a variety of professional associations and always including the personal factors so characteristic of both of the Gey's. Thus, none of

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*Presented at the Dedication of the W. Alton Jones Cell Science Center, Lake Placid, New York, June 9, 1971.

**Director, National Institutes of Health, U.S. Department of Health, Education, and Welfare.

you will be surprised that it was George Gey who taught my youngest son who asked to be here with me today, not only how to fish but how to catch fish. I am especially pleased to be here for the presentation of the George and Margaret Gey Library.

But let me return to the subject I first mentioned: The basic conditions necessary for science to prosper. We all know that brilliant and dedicated scientists throughout the ages have overcome adverse environments to make their contribution, and no doubt they will do so in the future. But the chances for progress will be immensely increased by adequate facilities and support, by maintenance of conditions favoring the freedom of thought which creative minds require, and by clearer public understanding of the relationship of science to society in this 20th Century, and the nature and limitations of the scientific approach. My old Chief at Oxford University, Howard Florey, believed that the discovery of the power of the experimental approach may prove to be the dominant feature of the 20th Century, and I agree. To him, the experimental approach was an exquisitely powerful instrument for seeking the truth.

There is today, I believe, much misunderstanding about the nature of the experimental approach. It is precisely the wrong instrument to chose if one's goal is to confirm a prejudice or an assumed position, and it is equally wrong to employ it when the nature of the problem does not lend itself to the experimental approach.

Some of this confusion has arisen from the rather general practice of equating the term <u>research</u> with the experimental approach. Today we use the word <u>research</u> to cover anything from a few hours' of light reading in

the library to Nobel Prize-winning studies. The term, biomedical experimental research, means precisely what it says. This type of research requires a jealous and almost fanatical dedication to seeking the truth about the most profound problems of living systems.

The history of this association and the purpose for which this building was constructed are dramatic examples of this point of view. Who among you could have foretold $2\frac{1}{2}$ decades ago the influence that information about cell nutrition, membrane kinetics, nuclear structure and function, and similar questions could have had upon such fields as virology, cancer, genetics, biochemistry, and molecular biology?

All of this reinforces Florey's basic belief that the experimental method has had a powerful influence on our society. It is also true that our society is now asking more of science than ever before. The irony is that we are not being asked for more truth, but simply more solutions to specific problems, failing to recognize that the results of experiments come out as they come out not as one wants them to come out. Some of the problems biomedical science is being asked to solve are almost exclusively in the domain of science--for example, delineating the precise relationship of diet to premature death from myocardial infarction or determining the basic conditions under which low level multiple potentially toxic materials in the environment may adversely affect human health. Other problems may become increasingly science-based challenges in the future, such as some of the particularly troublesome social and behavioral problems, as the social and behavioral sciences continue to mature and develop. Still others may never be the types of problems that lend themselves well to the experimental

approach. And here I would include most aspects of the familiar age old enemies of man--poverty, war, ignorance. Even in the area of disease where the experimental approach has produced such brilliant benefits, many areas are not science based problems. These would include cancer associated with cigarette smoking, some hereditary diseases where it seems unlikely that any methods other than selective exclusion of marriages will be effective, and some aspects of population and environmental problems, where motivation or social tradeoffs may be the dominant factors.

In general, these really serious problems of man have been resistant to major political and economic upheavals, and because in contrast there have been dramatic successes in research and technology, there is a growing demand that science solve such problems, wherher or not the problems have a science base. I would repeat: Science can only prosper if there is proper appreciation of the nature and limitation of the experimental method on the one hand, and the relationship of science to society, on the other.

But I would like now to speak specifically of the Cell Science Center which we dedicate today. In a real sense, this Center embodies one of the qualities of American life that most impressed de Tocqueville in his travels through this young nation in the last century: A talent for a voluntary association. The philanthropic aspect of this talent, it is true, reached its full flowering after de Tocqueville's time. But the initiative and drive of Americans in banding together to promote a worthy cause made a striking impression on the French observer. It was a quality that identified American effort, differentiating it from the pursuits of older, less innovative, more structured socieities of Europe. It is an important condition for science to prosper.

One of the continuing problems of the Tissue Culture Association over the years has been a lack of permanent facilities and the need for a stable source of financial support. The impetus for removing this obstacle has been provided through the generosity and vision of Mrs. Nettie Marie Jones, widow of W. Alton Jones, former Chairman of the Board of Cities Service Company. Mrs. Jones donated the land for this Cell Science Center, and a gift of $5.2 million by the W. Alton Jones Foundation, Inc.

The Center we dedicate today embodies most of our hopes for a field of study that has made enormous strides in this Century. Members of this audience have themselves written too much of this history for me to attempt to summarize it at this time. Tissue culture studies, in short, exerted a revolutionary influence on the course of basic and applied research in the second half of the 20th Century. Without this indispensable tool there would be no animal virology, and immunization as we practice it today would be impossible. Tissue culture has given us the means for extending and refining research in viral diseases, antiviral substances, cancer cellular transformations, genetic expression, macrobolecular synthesis, and cell differentiation, just to name a few of the areas now benefitting from the application of these techniques.

The environment for future progress will be better as a result of these new facilities. Further, the environment for progress in the future should be improved by reviewing, as you are doing today, the lessons of the last 25 years of the Tissue Culture Association. Such as:

. The productivity of attacking the long term profound problems rather than just the short term glamor areas.

- The importance of training the young scientists. Here the tissue culture course is the outstanding example.
- The clear examples you have provided for the understanding of the nature and limitation of science, as well as its tremendous contributions to society.

It should be clear to you by now that the two events we celebrate today fit quite well my sense of how the world should be. But these words honestly applied to this event, were prepared, as most of you know, against the background of what I believe to be an unfortunate and divisive debate over the best environment for cancer research to prosper in the future. This is not the proper platform to further this debate in a partisan fashion--nor can I in all candor appear before you at such a time without mentioning the subject. Thus, I shall simply restate in terms of what I feel is best for the American people, the concerns I have expressed consistently throughout this whole debate.

- That in the desirable and appropriate expansion of cancer research that the following conditions receive major consideration:
  1. The recognition that cancer is a science-based not a management-based problem. Thus, such expansion must build on the base of the progress in science so well demonstrated by this ceremony and the comments I have made about it.
  2. That cancer research remain within NIH.
  3. That cancer research remain within biomedical research.
  4. That the American people not be mislead by overpromise for cures. For the vast majority of life threatening cancers we simply do not know when or even if dramatic practical progress in prevention or cure will occur.

5. That the danger of adverse "politicalization" in science and disease be avoided.

Let me close by commenting on the timeliness of this ceremony in two respects:

. The whole of biomedical research is alive and vigorous as it has never been before--with greater promise than we would have dared dream 25 years ago. In fact, the cancer debate is but one clear example among many of the ferment in the field.

. After several lean years for Federal support of biomedical research, the 1971 budget and the President's 1972 proposed budget go far in terms of real dollars to overcome the decreases in program support support during the '67 - '70 period.

I am pleased to have been a part of these activites. Secretary Richardson and the new Assistant Secretary for Health and Scientific Affairs designee, Dr. Monte DuVal,both asked me to add their congratulations and and best wishes to my own--and my family's, as you continue in your service to science, your service to America, and your service to all mankind in these new impressive facilities of the W. Alton Jones Cell Science Center.

TAB 16

#675

THE MANAGEMENT OF NATIONAL RESEARCH PROGRAMS AND IMPLICATIONS OF THE CANCER INITIATIVE*

Robert Q. Marston, M.D.**

The proposal for a cancer moonshot coming as it has on top of several years of tight budgets, increased emphasis on targeted research and the growing belief among scientists of an inappropriate medical intrusion by Government into science, has shaken severely the biomedical community. An example of the depth of frustration felt by many was brought to me clearly in meetings with two representative groups of my own NIH scientists as recently as yesterday.

I come before you tonight neither to pour oil on troubled waters nor to fan the flames of concern which I know many of you have. Rather, my job is to discuss with you my views of the significance of the expanded cancer program in the larger domain of biomedical science, and the implications it may hold for the future management of national biomedical science programs in this country. As I begin, let me make a few quite candid comments.

First, and a bit facetiously, I worked so strongly, with the President's support, against the establishment of a separate cancer agency that the process of changing direction toward the compromise solution now supported by the Administration may cause

*Prepared for OST Seminar on "Role of the Executive Branch in Biological Science," July 31, 1971, Woods Hole, Massachusetts.

**Director, National Institutes of Health, U.S. Department of Health, Education, and Welfare.

me to leave behind a few skidmarks. Second, we do not yet know what action the House of Representatives will take on the cancer proposal. The Chairman of the Health Subcommittee, Congressman Rogers of Florida, continues to speak publicly and privately against the Senate passed S. 1828 largely along the lines so well expressed by Senator Gaylord Nelson in the Senate debate. I understand that Mr. Rogers plans to hold hearings after the August Congressional recess and that he has hinted that the hearings could turn into a searching inquiry into NIH as a whole. He is reported to have said that if the situation at NIH and at HEW is as bad as the cancer agency supporters say it is "then maybe we should look at the whole operation." Of course, I would welcome such a review and even suggest that the scope might be broadened to include all of federally-sponsored biomedical research.

A third and important point is the need to avoid "administrative paralysis" because of the continuing uncertainties. For this reason, I have instructed the Cancer Institute to proceed at full speed with the implementation of the 1972 expanded program and to place particular emphasis on drawing together the large number of scientists to participate in the development during the next few months of the more detailed plans called for both in the Senate Bill and by the President. Furthermore, I am receiving, on

a regular basis, progress reports which I am sharing with other Institute Directors and with the appropriate offices in HEW.

<u>The Cancer Program--An Example of Larger Issues</u>

The cancer issue did not emerge full blown like Minerva. Rather, it is a dramatic example of the much discussed question of the relationship of science to society: how to apply science to solving the urgent problems of mankind.

At some point the issue begins to turn on such questions as the appropriate level of national investment, targeted versus non-targeted research, basic versus applied, appropriate systems for the allocation of resources, public accountability, and the overall question of who shall make the decisions: scientists or non-scientists?

These are questions familiar to all of us. We have discussed them throughout our professional careers. But the questions facing us this summer are no longer academic. For no matter what the final action of the House of Representatives proves to be, we have in fact already embarked on the President's Cancer Conquest Program. The budget for cancer research has been increased impressively. Ann Landers did in fact generate a million pieces of mail in support of higher cancer appropriations. And, serious scientists are seriously concerned about the implications of all this for the whole of biomedical research.

The Basic Conditions Necessary for Science to Prosper

We all know that brilliant and dedicated scientists throughout the ages have overcome adverse environments to make their contribution and no doubt they will do so in the future. The pursuit of knowledge has become enormously expensive and public decisions have much greater influence on science than they had a hundred years ago. Its pace and directions can be altered by the voter. The chances for progress will be immensely increased by adequate facilities and support, by maintenance of conditions favoring the freedom of thought which creative minds require, and by clearer public understanding of the relationship of science to society in this 20th Century, and the nature and limitations of the scientific approach. The discovery of the power of the experimental approach may prove to be the dominant feature of the 20th Century. The experimental approach is an exquisitely powerful instrument for seeking the truth.

There is today, I believe, much misunderstanding about the nature of the experimental approach. It is precisely the wrong instrument to choose if one's goal is to confirm a prejudice or an assumed position, and it is equally wrong to employ it when the nature of the problem does not lend itself to the experimental approach.

Some of this confusion has arisen from the rather general practice of equating the term research with the experimental

approach. Today we use the word research to cover anything from a few hours' of light reading in the library to Nobel Prize-winning studies. The term, biomedical experimental research, means precisely what it says. This type of research requires a jealous and almost fanatical dedication to seeking an understanding of the most profound problems of living systems. The truths so found have brought great and totally unforeseen benefits.

Who among us could have foretold two decades ago the influence that information about cell nutrition, membrane kinetics, nuclear structure and function, and similar questions could have had upon such fields as virology, cancer, genetics, biochemistry, and molecular biology?

All of this reinforces a basic belief that the experimental method has had a powerful influence on our society. It is also true that our society is now asking more of science than ever before. The irony is that we are not being asked for more truth, but simply for more solutions to specific problems. However, as scientists we recognize a fact that society at large tends to forget; namely, that the results of experiments come out as they come out not as one wants them to come out. Some of the problems biomedical science is being asked to solve are almost exclusively in the domain of science--for example, delineating the precise relationship of

diet to premature death from myocardial infarction or determining the basic conditions under which low level multiple potentially toxic materials in the environment may adversely affect human health. Other problems may become increasingly science-based challenges in the future, such as some of the particularly troublesome social and behavorial problems, as the social and behavioral sciences continue to mature and develop. Still others may never be the types of problems that lend themselves well to the experimental approach. And here I would include most aspects of the familiar age-old enemies of man--poverty, war, ignorance. Even in the area of disease where the experimental approach has produced such brilliant benefits, many problems are not science based. These would include cancer associated with cigarette smoking, some hereditary diseases where it seems unlikely that any methods other than selective exclusion of marriages will be effective, and some aspects of population and environmental problems, where motivation or social tradeoffs may be the dominant factors.

In general, these really serious problems of man have been resistant to drastic political and economic remedies. In contrast there have been dramatic successes in research and technology, and as a result of these successes there is a growing demand that

science solve the problems of humanity, whether or not the problems have a science base. I would repeat: Biomedical science can only prosper if there is proper appreciation of the nature and limitation of the experimental method on the one hand, and the relationship of science to society, on the other.

I pointed out these concerns in testimony before the Senate Appropriation Committee last week. The underlying ideas have been well expressed recently in editorials in the New York Times, The Washington Post, The Evening Star, The New England Journal of Medicine, and Modern Medicine as well as by others. Furthermore I anticipate that they will be a matter of discussion tonight and tomorrow night at the seminar.

<u>The role of the scientist</u>: I want to insert here some comments that I found difficult to write about the role of the scientist. I say difficult because I do not plan to take the time before this audience to attempt to give a balanced view -- pointing out the great credit that American biomedical scientists deserve for putting this nation's competence to the very forefront among all nations or to talk about individual scientists as I have known them over the years. Rather I want to insert a word of concern that the current climate will invite, perhaps even demand, the crystallization of other attributes that scientists hold in common with all mankind. It would be perfectly natural to read

into the cancer action the message that now is the time to grab support for one's own field blindly even greedily; that now is the time to oversell the importance and potential of one's own area of interest to lay interpreters who may be only too ready to receive such promises. Such activities can possibly be reconciled with a sense of responsibility on the basis that the end justifies the means.

Governments and Biomedical Science Policy

Recently I was asked to participate in a symposium sponsored by the public relations representatives of American medical schools. My assigned topic was the statement "Research must be Sustained." My first point was that research does not have to be sustained. 1967 did happen. We did have a decrease of support in the U.S. Indeed the question of the appropriate level of support for biomedical research remains one of the most persistent and most important questions around. This problem occurs in all governments. The U.S.A. now supports in one way or another about 50 percent of the biomedical research in the world but our problems are very similar to those experienced by such diverse governmental systems as the highly organized Scandanavian countries, the supposedly secure medical research council mechanism of the United Kingdom, and the research programs which have grown so rapidly and under different types of pressures inside Japan. My point is that the

question of the level and the mechanisms for the support of biomedical science have remained remarkably similar whether one looks at studies over the last decade and a half of NIH itself or whether one looks across large, middle size, and small Governments. A major point of difference has been the development in this country of the very effective technique of tying the request for investment in biomedical science to highly visible disease entities. This practice tends to obscure the normal governmental concern for stewardship in the expenditure of public funds, and affect the evaluation priority among different fields. Although I anticipate that for variety of reasons we will see over the next year or two, substantial increases as a result of the appeal of the categorical objective, I also see as almost inevitable a braking action due to a reordering of national priorities similar to the 1967 - 1970 period. I think it's worth while focusing on two key elements that are ever present in Federal stewardship. The first is the level of effort and the second is the issue of targeted versus non-targeted research. Despite all of the past expressions of worry and concern about the level of effort, I find that the most compelling case that can be made is in behalf of support for a significant component of the Nation's talent in the basic biomedical areas; that the distribution of this support should be based on an assessment of quality and fairness; and that wide fluctuations, especially downwards, should be avoided, since they are markedly disruptive.

Let me suggest for your consideration that the level of effort is defined in this country as well by our peer review mechanism as by any other. The general characteristics are that about 50 percent of the projects submitted are deemed scientifically meritorious. I would submit that an appropriate national research allocation might be to insure that no field receive less than enough to pay somewhere between 50 and 75 percent of the meritorious applications. Beyond that point, a decision might be made to place special emphasis on those regular research grants that fall in the field of public interest such as cancer, heart, genetics. A public policy of this character would handle a major continuing concern and debate in the question of Federal policy.

The question of targeted research is a more profound question and is at the heart of the cancer issue. On the one hand, intelligent people know that simple assertion of a desire to solve a complex problem gives no assurance of success; on the other, there are clearly advantages in science in focussing attention on specific problems.

By way of preface some semantic underbrush should be cleared away by explicitly stating that all research scientists work towards targets and that all research is targeted on specific goals and objectives. Nevertheless, the patois of research administration has coined the term <u>targeted research programs</u> to describe a vaguely

and imprecisely bounded subset of research activity.

One sense in which the NIH has used the term would state that targeted research programs originate when a domain of science reaches a stage of maturity that makes possible consenus by experts: that a specific, concrete and important objective whose realization would have a significant impact on an important health problem has been identified; and that if materiel and personnel resources are effectively marshalled to pursue the objective, the probability of success is high. In this sense, program means that the participants knowingly participate in an organized and deliberate pursuit of the objective or target. Implicit is the fact that the effort is carefully planned, and on a scale that can foresee needs and define requirements with specificity over several budget cycles. The planning is highly centralized and its execution is monitored, controlled, coordinated and integrated by an overall central focus for governance. As the scale of the program enlarges, more elaborate requirements for rapid communications between participants increase and the central point of governance tends to act as a switching station. The plan includes the specification of subobjectives. The criteria for determining the extent of progress toward objectives and subobjectives are explicitly stated before the work is undertaken, progress is periodically and systematically

evaluated against these criteria, and decisions to continue or terminate a line of pursuit are taken on this basis.

In this sense the role of the expert in target selection and in the planning of the effort is central.

The term targeted research program has been used in another sense, that is, a marshalling of resources to attempt to attain an objective that is devoutly and urgently desired--by science or by society--even though that objective is not one whose attainment can be mapped out in detailed actionable terms and with confidence of success. The moving force is a broadly held conviction that the seriousness of the problem warrants a substantial effort even though the prospects of success are slim.

Some of the important basic attitudes toward targeted research programs would seem to include the following:

- Targeted programs should not compete with level of effort supported research; each should be justified in detail and added to a reasonably sustained and stable system of research.

- Targeted programs of the type first mentioned; those characterized by the identification of an important objective, attainable in principle and highly likely to succeed in practice if pursued with sufficient resources should be pushed with vigor by an Agency such as the NIH.

Targeted programs of the second type present a difficult problem. There has really never been a test of the proposition that important headway will be made if enough resources are focused sharply on an intractable problem. Even though most scientists are uncomfortable supporting this proposition, there is some evidence-- if I read Project Hindsight correctly--to support it. Provided a substantial level of effort investment has been insured, and provided these "targets of hope and aspiration" are recognized for what they are, particularly by the Congress and by society, my disposition is that scientific community should be responsive to these expressions of societal desire.

Just as research must be sustained, so also must be the development of research manpower. The NIH has been under the gun, formally since mid April 1970, to rationalize and justify its training investments. In response, a major effort has been started to provide empirical data and analyses relevant to the problem. Irrespective of what specific information emerges, however, it is clear that the nation's academic institutions must continue a high steady level of production of carefully trained research workers if we are to sustain our national research programs.

Attrition rates for the pool of research manpower are high, particularly in the case of physicians. Obviously a major expansion of national research efforts, such as that envisaged by the Cancer Conquest Program, would be manpower limited for some years.

No unanimity is presently apparent on the issue of the nature and magnitude of the Federal role in training, but at this point in history, I doubt that Federal research objectives can be attained without continued and substantial Federal investments.

I have laid before you some of the thoughts and concerns that have preoccupied the NIH in recent months. I hope these can serve as take off points for a productive dialogue. Thank you.

TAB 17

#675

Progress and Problems in Heart and Lung Research *

Robert Q. Marston, M.D.
Director
National Institutes of Health
U.S. Department of Health,
Education, and Welfare

Mr. Eliason, Dr. Vogel, and honored guests:

It was with great pleasure that I accepted your kind invitation to take part in the dedication ceremonies for the Santa Barbara Heart and Lung Institute.

The people of this area have made an enduring commitment to better health. I congratulate you on your achievement and look forward, with you, to a bright future.

I believe the future for heart and lung research is indeed promising. This evening I would like to review briefly current and proposed efforts in this field, drawing primarily on the experience of the National Institutes of Health.

The acute heart attack remains our Nation's most serious health problem. Nobody knows for sure how many heart attacks occur each year in the United States, but the current estimate, which may be conservative, is 1 1/4 million, almost half of them fatal.

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*Presented at the Dedication of the Goleta Valley Community Hospital, Santa Barbara, California, August 6, 1971.

The intensive coronary care unit, which began to come into fairly widespread use during the 1960's, has substantially improved the prospects of survival for those heart-attack victims fortunate enough to be cared for in such a facility. In particular, instrumentation permitting continuous monitoring of the patient, coupled with the ready availability of emergency drugs, resuscitation equipment, and highly trained medical personnel, has sharply reduced the number of so-called "electrical deaths" resulting from heart rhythm disturbances. The ICU's have demonstrated that the earliest detection and vigorous treatment of even slight, seemingly inconsequential abnormalities in heart rhythm may often forestall the later development of serious arrhythmias leading to cardiac arrest. And even the heart that has been brought to a standstill by refractory arrhythmias can often be restarted and heartbeat sustained by modern defibrillation and artificial pacing techniques.

The ICU's have saved many thousands of lives that might otherwise have been lost, and they have taught us quite a bit about preventing and dealing with some of the potentially lethal complications of the acute heart attack. Yet it is startling how little we still know about the acute phase of the heart attack: that period beginning with the onset and lasting for 4 to 5 days when the threat to the patient's life is greatest.

If we are to continue to improve the clinical management of acute heart attacks and thereby increase the survival rate among heart-attack victims, we need to learn a great deal more about the premonitory symptoms, the precipitating factors and the presently unpredictable clinical course of the acute episode, as well as the mechanisms that operate in its potentially disastrous complications. We must also thoroughly evaluate existing methods of treatment and rehabilitation, test potentially promising new procedures, and to seek to improve all of them. To do this requires the most intensive study of heart-attack patients.

Currently in operation with NIH support at nine medical centers throughout the country are Myocardial Infarction Research Unites, or MIRU's, that combine unexcelled patient care with intensive clinical research on the acute heart attack and its complications. The purpose of these Units is to improve medical knowledge of the acute attack itself, including the identification of factors that critically affect the outcome of the illness, and to develop new or improved methods of diagnosis and treatment.

Supplementing the clinical activities of each MIRU is an extensive program of laboratory research and experimental studies in animals. The animal studies permit far more detailed observations than are presently possible in patients and also

extensive testing of new drugs or other therapeutic measures that may be applicable to clinical problems.

The MIRU carries into clinical research the patient-care concepts developed in the intensive coronary care unit and in the diagnostic cardiac catheterization lab. We are hopeful that the new knowledge gained through this research will make possible further substantial reductions in mortality among heart-attack patients.

Another research approach, presently confined to laboratory and animal experimentation, is concerned with finding means of protecting heart muscle against the destructive effects of blood deprivation after an acute heart attack. The goal is to reduce the extent and severity of permanent heart damage.

A dreaded complication of acute heart attacks is cardiogenic shock, which formerly carried mortality rates as high as 95%. Improved therapeutic measures, especially the availability of certain drugs, have reduced this appalling mortality somewhat--to about 85%--but cardiogenic shock still accounts for about 1/3 to 1/2 of hospital deaths from heart attack. We are working to improve the outlook for these patients through drug therapy and through the use of mechanical devices to assist the overburdened heart.

Sudden cardiac death, or death before hospitalization, accounts for about one-half of our 600,000 annual deaths from artheriosclerotic heart disease. This large number of very sudden

and very early deaths necessitates a better understanding of the acute disease process and the development of new modes of therapy.

It may also indicate the need for early availability of medical care, although preliminary studies suggest that a major cause of delay in treatment is the patient's procrastination in seeking help and knowing how to seek it rather than in the responses to that call, at least in many urban communities. Thus, there is a great need for a community educational program to reduce delay in hospital arrival time.

So vast is our ignorance of the factors involved in sudden cardiac death, and so urgent is our need for this information, that the Myocardial Infarction Program of the National Heart and Lung Institute has awarded no less than 17 research contracts for the investigation of various aspects of this problem alone.

The goals of this broadly based research program include the identification of factors that precipitate or "trigger" acute heart attacks, that increase susceptibility to lethal heart attacks and contribute to their rapidly fatal outcome, and the identification of premonitory signs and symptoms that may warn the patient or his physician of an impending attack in time to institute preventive measures or hospitalization.

Only through the acquisition of this knowledge can we develop practical methods of treatment for the very early stages of the acute heart attack.

I note with great satisfaction that the Santa Barbara Heart and Lung Institute plans an active surgical program for the treatment of congenital and acquired heart defects, for there is still a great opportunity to increase our application of existing knowledge and expertise in the field of cardiovascular surgery as well as a need to broaden those capabilities through further research.

Despite dramatic decrease in the incidence of new cases, thousands of Americans are still ravaged by the sequelae of rheumatic fever, for example, patients whose scarred, deformed heart valves require surgical replacement with an artificial valve or valve graft. Even with the imperfect state of development of existing valve substitutes, their use restores normal or near normal activities, including in many cases the capacity to engage in strenuous occupations, to well over 80% of valve recipients. And steady progress in the evolution of new valve substitutes, their materials, fabrication and use, has greatly enhanced their performance characteristics while minimizing valvular deterioration and thrombo-embolic phenomena.

Perhaps the greatest single research advance against rheumatic fever and its sequelae, rheumatic heart disease, was the identification of group A hemolytic streptococcal infections as the first link in the chain of events leading to the characteristic heart valve deformities and/or heart muscle damage of rheumatic

heart disease. This information plus the development of tests for the early rapid diagnosis of strep infections makes it possible to prevent rheumatic fever by antibiotic treatment of susceptible individuals.

Preventive approaches to coronary heart disease are also a major concern of NIH. For the individual who makes it to the hospital, life may be greatly prolonged, and suffering and disability greatly reduced by advances in clinical management. But this is a disease which exacts its heaviest toll outside the hospital, in some as sudden and unexpected death, in others as chronic suffering or disability. All of the most modern coronary care units with the finest equipment for restoring, pacing and monitoring heart rhythm and performance, and for circulatory assist implants and transplants are of no avail for patients who are dead on arrival. Against this particular threat, which hangs over so much of adult civilized man, primary prevention is the only hope of solution.

Population studies have taught us that the candidates for this mortality, while outwardly healthy, are seldom without certain underlying features, or "precursors". The characteristics of a kind of "coronary profile" are emerging which can be used to identify the potential coronary candidate early enough to take preventive measures. For example, the coronary candidate generally tends to

have somewhat high levels of certain lipids in the blood, high blood pressure, and to smoke cigarettes. He may be emotionally aggressive and hard-driving but physically sedentary and overweight. Some of the features can be modified with the help of a physician, so that identification of the high-risk individual could enable the physician to reduce the associate risk. Reduction of blood pressure and cessation of smoking are two of the approaches which hold the greatest preventive promise at present. Reduction of blood lipids is more controversial, but probably of considerable importance to those with specific disorders of blood lipid.

The relationship between dietary habit patterns and blood lipid levels is well documented, especially the effects on blood lipids in the amounts and kinds of fat in the diet. More recently we have recognized that dietary carbohydrate or total calories may be more important than dietary fat in <u>some</u> lipid disorders. In this connection, we have learned that specific therapeutic diets must be directed against the particular blood-lipid abnormality present; because an excess of fatty materials in the patient's blood may indicate any one of five distinct lipid-transport disorders, each one different in its clinical signs, risk for the patient, and responsiveness to diet or drug treatment. Some of these hyperlipoproteinemias carry far more risk than others, and warrant far more drastic and early intervention with the appropriate

dietary or drug treatment to prevent cardiac disability later in life.

Meanwhile, however, the patient derives no sense of danger or disability from the mere presence of an abnormal lipid pattern in his blood. This involves us in a problem of motivation which is familiar to any practitioner of preventive medicine but which is apt to prove especially challenging for those who would attack the public health problem of coronary heart disease by correcting its all-too silent, comfortable, chronic and deadly precursors. How shall we persuade the person with an undisturbed sense of well-being to adopt a permanent change of life-style that immediately disturbs his sense of well-being? The first step, of course, is to find him. Then, to explain what he has at risk may be persuasive in itself. Long ago, we saw that people could be moved to take appropriate action when tuberculosis was unexpectedly revealed on their x-rays. But this problem of motivation shows some new facets where the precursors of heart attacks are concerned. One of these is the generally open-ended--even interminable--nature of both the treatment and the condition being treated in most cases.

All of this is similarly true of the blood pressure elevations which constitute another extremely potent risk factor and precursor of arterial occlusions. About 20-25 million

Americans are estimated to have abnormally high blood pressure. Again, blood pressure elevations too slight to be sensed by the patient are risky enough to warrant medically reducing them to normal, And again, the condition--essential hypertension--is chronic and cannot be cured; only controlled by continuing the treatment throughout life.

Still, a great variety of superb drugs have become available for this purpose, making possible a full and healthy life for those whose hypertension is detected early, and who adhere to the medication prescribed for them. Since the blood pressure can now be reduced to safe levels by treatment, the great present need is for practical methods of detecting the many untreated hypertensives known to be at large in the community, and ascertaining whether they can be motivated and maintained on the effective treatment methods available and whether the same dramatic benefits accrue to the mild or labile hypertensive as the severe hypertensive. This massive problem of screening, testing, and motivation will be attacked in large-scale community studies now being launched for the NHLI.

Similarly, with respect to the hyperlipidemias, six Lipid Research Clinics are now being established at various medical institutions, with the support of NIH funds; and additional clinics will be established in the future. These clinics will carry out

targeted research directed toward the prevention of premature atherosclerosis through the identification and treatment of individuals rendered highly susceptible to the disease by the blood lipid abnormalities mentioned earlier.

Prevention is also the key to the eventual control of certain of the chronic lung diseases, notably emphysema, that have been assuming alarming proportions as a health problem during the past 20 years.

We are becoming ever more proficient in dealing with acute respiratory crises, such as the respiratory distress syndrome of hyaline membrane disease, the leading cause of death among newborn infants. Intensive respiratory care units, which are developing along lines similar to those of the intensive coronary care unit, promise to improve still further the salvage of patients suffering from life-threatening respiratory crises.

The problem is that, while we can sustain the patient's failing respiratory system for a few hours, or even for a few days with drugs, blood oxygenators, or other respiratory-assist techniques, we cannot undo the permanent damage that his lungs have sustained. Progress in the long-term clinical management of chronic lung disease has been disappointingly slow.

Since the damage done to the lungs by emphysema cannot be undone, the development of reliable pulmonary function tests for

early detection of the disease is urgent. During the past decade, NIH-supported research has contributed to the development of a wide variety of tests yielding reliable indices of lung function. These tests have proved highly useful in detecting and assessing deterioration in lung function due to emphysema and other causes before they are clinically symptomatic.

Of particular importance toward the early detection of pulmonary diseases in general practice or in the health screening of large numbers of people has been the development of simple, rapid, single-breath tests of lung volume, ~~and~~ gas exchange, and maximum rate of exhaling. The widespread application of such diagnostic tests is contributing to more frequent detection of emphysema during its early stages, when the physician is better able to initiate measures for halting further progress of the disease.

I have covered in a very general way some of the prominent areas of heart and lung research, and some of the things we are concentrating on at NIH. I would like to conclude by mentioning the necessity to maintain balance and perspective in these areas of research and to note their relationship to the larger universe of biomedical research. I make these rather self-evident points because we seem to be in a period when the demand for short-term and dramatic results threatens to distort our scientific priorities and overwhelm our scientific resources. Progress in heart and lung

research, as in other fields, still depends on increased human knowledge and understanding and on steady pursuit of the profound and long-term problems facing us.

We have made enormous strides in this country because of this kind of pursuit, along the entire spectrum of biomedical science. We must avoid both overpromise and the kind of compartmentalization that will fragment and weaken our total research effort. Heart and lung research can thrive best in an equally thriving research environment.

It seems to me that this is the kind of environment you are creating here at the Santa Barbara Heart and Lung Institute and I congratulate you for it. I am sure that in the years to come its record of achievement in research, patient care, and community services will be a proud one.

TAB 18

#682

HEALTH CAREERS*

Robert Q. Marston, M.D.**

Good morning. I'm very pleased to have been invited to speak with you about the most valuable possession you have--your future. Most of the time you hear someone say that you can bet he's a minister--or an insurance salesman--or your father. I'm none of these, of course. I'm also not the fellow who writes the astrology column in the newspaper.

Given the kinds of things that are now happening in today's medicine, you don't need much foresight to see where we are headed. We are looking forward to steady progress in research. Each year, we understand more about such health menaces as cancer and cardiovascular disease. Each year, our medical armamentarium improves.

We are looking forward to new frontiers with an increasing understanding of the life process and its mechanisms.

And we are looking forward to a supply of able persons in all the health professions and occupations to enable every American to have access to medical care whenever and wherever it is needed.

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* To be delivered at the Mississippi Health Expo I, Jackson, Mississippi, October 1, 1971.

**Director, National Institutes of Health

That is certainly a desirable objective for the American future. You can see yourself in it, raising a family of healthy children, free of worry that medical care is unavailable in your community, assured that good medical care and the benefits of medical research are available to even the poorest families. To enjoy all these benefits you are going to have to help make it happen.

It takes a lot of people to keep this country healthy. I could give you a list of numbers and occupations that would add up to some 4 million people working in the health field today. Maybe that doesn't mean much to you, so let me put it this way: That is almost twice the number of people in all of Mississippi. The nation's health workers--and that includes doctors, nurses, dentists, hospital administrators, technicians and everybody else working in the health field--could fill 2,000 auditoriums the size of this one. The staff of the National Institutes of Health alone would fill a little over half of the seats in this coliseum.

And yet this isn't enough. In many areas--the inner city and rural areas in particular--the services of skilled health professional are difficult to obtain. Moreover, unless some action is taken--unless more people like yourselves decide to undertake careers in the health field the situation will worsen. By 1980, the nation's population is expected to increase by 24 million. Much of that increase will be in those groups that require the most health services

the very young and the very old. Increased personal income, more education, more insurance coverage, and more efforts to bring medical care to the disadvantaged are other developments which will be adding to the demand for services that require well trained health workers.

Where are all these health workers going to come from? The answer is right here-from among people like yourselves, in this audience--from among the millions of young people now in high schools and colleges across the country.

Among young people today there is a great concern for the individual and for human dignity.

This new generation is also a questioning generation, unsatisfied with old concepts, looking for the truth even where any answer is difficult to find.

And today's young people want action--the excitement of discovery and accomplishment--and the satisfaction of having performed well in an important task.

These are the kinds of cravings that can be satisfied in the health field--in more than 125 different kinds of professions and occupations--administrators and technicians, social workers and environmental health workers, and secretaries as well as in the usually thought of professions of medicine and nursing. They are all

part of what the NIH Bureau of Health Manpower Education has labeled the "Life Corps."

They have a 30-second television announcement often seen during football games. Its challenge is as straightforward as a fullback play through the center of the line. "You could wait a lifetime to help somebody," the television spot says, or "you could spend a lifetime at it."

How do you get ready to serve the health needs of other people? It takes many of the qualities I have mentioned--and which I think you have--and it also takes a willingness and ability to learn. It's true, you can get some of these jobs with six months of training, but others may take eight, ten, or twelve years or more of study after high schools. The requirements of these jobs are tough, and you might as well face it. To become a physician usually takes four years of college, three to four years of medical school, and another year at least of internship and several years of formal training while giving service.

To become a dentist, you will need at least two to four years of college plus four years at a school of dentistry. A pharmacist needs five to six years of college study. A veterinarian needs a minimum of six years of training after high school. It takes from two to four years of training to become a registered nurse. But health careers require devotion to learning and study all your life.

But not everyone wants to become a physician, or dentist, or a veterinarian. At the turn of the century one out of every three health workers was a physician. Today, one out of every ten health workers is an M.D. The largest numbers of health job opportunities are in activities providing the technical and supporting services essential for the prevention, diagnosis, and treatment of disease and illness.

Some of these jobs require considerable training, too. More than four years of college, for example, are necessary to become an occupational therapist, physical therapist, dietitian, or medical librarian. Four years of college can qualify you for a job as a medical technologist. Careers such as dental hygienist, dental assistant, dental laboratory technician, inhalation therapist, or radiologic technologist require less college preparation.

On-the-job or short-term special training after high school may prepare a student for important jobs, such as medical secretary, nurse aide, orderly, certain kinds of technicians, laundry manager, and many others.

Where can you work in the health field? It is a function of how much study and effort you are able and wish to put into it. The field is large enough to accommodate virtually every interest and every ability.

When labor is in short supply, new opportunities are available to people who want to work in the field. This law of supply and dema

works to your benefit in the health field. For example, recognizing the need for more health professionals, Congress has provided for loans and scholarships to help ensure students, regardless of economic background, the opportunity to enter health careers that require a long period of education and training. It will be most important as you pursue your careers to become familiar with Federal and other sources of financial assistance that may enable you to complete your formal period of education in a health occupation.

Grants are available also under the Educational Opportunity Grants Program for undergraduate students in exceptional financial need who would otherwise be unable to complete their education. Other sources of financial aid are the National Defense Student Loan Program and the G.I. Bill. There are programs in several Federal agencies to support specialized training and education.

These would be minor incentives if the careers these programs lead to did not offer opportunity for service and self-fulfillment as well. These opportunities are offered to all who qualify.

A major effort is now underway to increase the opportunities for all capable students in the health field at all levels and we have been making much progress along these lines.

We are making progress in many ways. Problems of making good health care available when it is needed have always plagued us. Able and dedicated people are in short supply to give these services. We

intend to see that it does not continue. Through the legislation now pending in Congress we hope to raise the size of our graduating class of physicians from this year's 9,500 to more than 17,000 by 1980. Steady progress toward this goal would mean the end of the physician shortage by the end of the 1970's.

By 1980 we also hope to be graduating nearly 6,000 dentists each year, an increase of nearly 1,400 over this year's graduating class.

By the end of the decade we also hope we will have met the expected need for registered nurses, licensed practical nurses, and aides required to give safe and effective care.

You can be among these future graduates. Or you may want to be among the allied health personnel we will be needing by 1980.

The opportunities are there. The need is there. The rewards are there.

Early this year President Nixon reviewed the nation's health programs for Congress. "Things do not have to be this way," he said. "We can change these conditions--indeed we must change them if we are to fulfill our promise as a nation. Good health care should be readily available to all of our citizens."

You can choose to have a part in achieving this national goal.

TAB 19

BACKGROUND INFORMATION ON THE ORGANIZATION AND BUDGET OF THE NATIONAL INSTITUTES OF HEALTH[1]

Robert Q. Marston, M.D.[2]

Page

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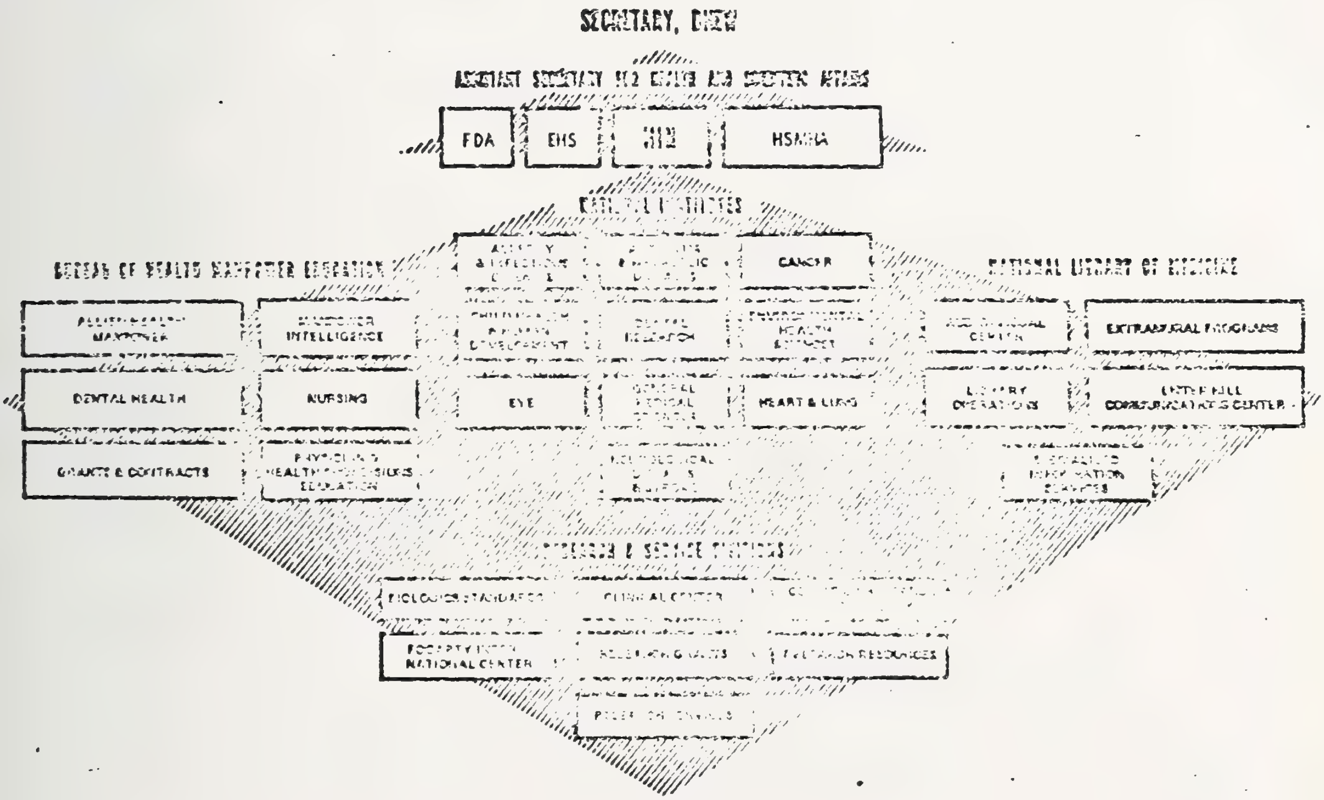
[1]Prepared for Association for Academic Health Centers, Grand Bahama Island, October 2, 1971

[2]Director, National Institutes of Health, U.S. Department of Health, Education and Welfare

I. ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH



Principal Officers, National Institutes of Health:

Director	Dr. Robert Q. Marston
Deputy Director	Dr. John F. Sherman
Deputy Director for Science	Dr. Robert W. Berliner
Director, Bureau of Health Manpower Education	Dr. Kenneth M. Endicott
Director, National Library of Medicine	Dr. Martin M. Cummings
Associate Director for Health Manpower	Dr. Leonard D. Fenninger
Associate Director for Program Planning and Evaluation	Dr. Thomas J. Kennedy, Jr.
Associate Director for Administration	Mr. Richard L. Seggel
Associate Director for Communications	Mr. Storm Whaley
Associate Director for Clinical Care	Dr. Thomas C. Chalmers
Associate Director for Extramural Research and Training	Dr. Ronald W. Lamont-Havers
Assistant Director for Collaborative Research	Dr. Leon Jacobs

II. NIH BUDGET COMPARISON, 1970-1972

By Appropriation
(Amounts in thousands)

	1970 Actual Obli-gations	1971 Appro-priation	1972 Appro-priation	Change 1972 Over 1970
Institutes & Research Divisions				
Biologics Standards................	$8,235	$9,296	$9,205	$+970
National Cancer Institute..........	181,345	233,160	337,531	+156,186
National Heart & Lung Institute....	160,258	194,925	232,107	+71,849
National Institute of Dental Research..........................	28,716	35,440	43,388	+14,672
National Institute of Arthritis & Metabolic Diseases..............	131,453	137,986	153,164	+21,711
National Institute of Neurological Diseases & Stroke................	97,164	103,502	116,590	+19,426
National Institute of Allergy & Infectious Diseases.............	97,055	102,368	108,710	+11,655
National Institute of General Medical Sciences................	148,090	160,194	173,515	+25,425
National Institute of Child Health & Human Development..............	75,962	94,760	116,833	+40,871
National Eye Institute............	22,805	30,032	37,256	+14,451
National Institute of Environmental Health Sciences.................	17,254	20,151	26,436	+9,182
Research Resources................	66,932	66,320	74,948	+8,016
Fogarty International Center.......	2,731	3,666	4,288	+1,557
Subtotal, IRD's.......	1,038,000	1,191,800	1,433,971	+395,971
National Library of Medicine.........	19,758	21,440	24,086	+4,328
Other................................	8,215	8,903	15,007 [1/]	+6,792
Bureau of Health Manpower Education..	392,084	432,310	184,620	-207,464
Total, NIH........................	1,458,057	1,654,453	1,657,684	+199,627

1/ Includes $3,565,000 for Buildings & Facilities.

NIH BUDGET COMPARISON 1970-1972
By Activity
(Amounts in thousands)

	1970 Actual Obligations	1971 Appropriation	1972 Appropriation	Change 1972 Over 1971
Inst. & Res. Divisions				
Research grants	592,352	662,272	796,478	+204,126
Trng. grants & fellowships	178,907	182,286	192,392	+ 13,485
Collab. Res.(mostly contracts)	124,845	184,489	269,285	+144,440
Intramural research	91,996	113,004	118,585	+ 26,589
Other direct operations	49,900	49,749	57,231	+ 7,331
Subtotal, IRD's	1,038,000	1,191,800	1,433,971	+395,971
National Library of Medicine	19,758	21,440	24,086	+ 4,328
Other	8,215	8,903	15,007 1/	+ 6,792
Subtotal	1,065,973	1,222,143	1,473,064	+407,091
Bureau of Health Manpower Education				
Medical, dental & related health professions	281,173	311,690	62,550	-218,623
Nursing	61,701	74,550	61,690	- 11
Public Health	17,721	18,482	19,044	+ 1,323
Allied Health	13,503	19,415	30,654	+ 17,151
Program dir. & manpower anal.	4,471	5,090	6,682	+ 2,211
Other	13,515	3,083	4,000	- 9,515
Subtotal, BHME	392,084	432,310	184,620	-207,464
Total NIH	1,458,057	1,654,453	1,657,684	+199,627

1/ Includes $3,565,000 for Buildings and Facilities

III. PENDING BILLS AFFECTING NIH'S ORGANIZATION

Health Manpower Legislation

Authority for Federal support of health professions and nursing educational programs expired on June 30, 1971. P.L. 92-52, enacted July 9, extends student aid provisions at last year's funding level. Both the House and Senate have passed bills amending the Health Professions Educational Assistance Act and the Nurse Training Act, but at this writing conferees had not yet resolved their differences, though agreement is expected imminently.

The Appropriations Committees were unable to act on the President's budget request for health manpower at the same time they considered the rest of the budget. Hearings for a supplemental appropriation are expected to begin soon after a compromise bill is enacted. If the new legislation is not enacted and funded by mid-October, serious problems of implementation are expected.

Health Professions Educational Assistance

Despite major differences, discussed below, the bills now before the conference committee reflect agreement on several basic principles arising out of experience with earlier legislation and public concern with the Federal role in health manpower training.

Capitation: Both bills provide substantial support to health professions schools based on enrollment, based on the principle that a predictable level of Federal support is essential for the schools' continued financial stability. Capitation formulas in both bills vary according to profession, with medicine, osteopathy, and dentistry receiving preferential treatment.

Broadened authorities: Both bills embody the essential features of the Administration's "health manpower educational initiative award" proposal, which would permit assistance to agencies, organizations, and institutions, and combinations thereof, as well as to schools, for a variety of purposes. A new contract authority for these purposes is also provided.

Construction: Both bills attempt to deal with the problem of increasing demand for Federal construction support through a system of loan guarantees and interest subsidies to supplement construction matching grant authority.

<u>Start-up grants</u>: Both bills provide substantial support for new schools of medicine, osteopathy, and dentistry in the form of a lump sum or capitation.

<u>Shortage areas and specialties</u>: Attempts to influence the distribution of physicians by geographic and specialty areas are evident in both bills. Special training programs and favorable loan forgiveness provisions are the approaches most favored for these purposes.

<u>Categorical training</u>: Both bills include provisions for specialized training programs. In addition to family practice training--primarily a question of shortage--the final bill may include provisions for training in pharmacology, nutrition, or drug abuse.

<u>Financial distress</u>: While both bills continue authority for assistance to schools in financial distress, funds are limited to a percentage of project grants or a separate (and decreasing) authorization, in the expectation that increased capitation support will eliminate the need for distress grants.

<u>Disadvantaged students</u>: Student aid provisions in both bills favor the disadvantaged. Special project (House) and capitation (Senate) provisions would also encourage enrollment of disadvantaged students.

<u>Sex discrimination</u>: Both bills prohibit schools from discriminating in admissions on the basis of sex.

Key issues still to be resolved include the following:

<u>Enrollment increase</u>: The House bill reflects the committee's strong conviction that schools should continue to increase output in order to qualify for Federal support. The Senate bill has no mandatory increase but would encourage expansion through differential capitation formulas.

<u>Program plan</u>: Under the Senate bill, eligibility for capitation grants is conditional upon accomplishing three of nine program objectives; schools would submit a plan to DHEW for approval. The House bill has no such provision.

<u>Entitlement</u>: An important issue is whether or not capitation payments are entitlement grants which must be funded. The alternative approach is to prorate available funds according to the formula established for capitation for the various professions.

Student loans: The Senate bill amends the Higher Education Act of 1965 to make health professions students eligible for guaranteed loans; the House bill does not. At the same time, loan forgiveness features of the House bill would extend to all educational loans, while the Senate bill provides forgiveness only to loans made under the Public Health Service Act or through the Office of Education.

Foreign students: The Senate bill allows loans and scholarships for American students studying abroad, under certain circumstances; the House bill does not.

Selective service: Also limited to the Senate bill is a provision which would substitute four years of service in a shortage area for the "doctor draft."

Nurse Training

Many of the principles embodied in the HPEA bills are also featured in the nursing bills now in conference--notably capitation, construction loans, broad authority for innovative programs, and student aid provisions which favor disadvantaged students and encourage practice in shortage areas. Both bills retain expansion of enrollment provisions of the current law. The Senate bill requires fulfillment of a program plan in order to qualify for capitation grants. Both bills include student loan amendments similar to their HPEA counterparts, but simply extend current scholarship provisions with a higher limit on individual awards. Both bills require that schools applying for aid give assurances that their admissions policies are not sexually discriminatory.

Comparison of Pending Cancer Legislatives Proposals

ISSUE	EXISTING ORGANIZATION	S. 1828 (AS PASSED BY SENATE)	H.R. 10681 (Rogers, 9-15-71)
Location of Responsibility for Cancer Research	National Cancer Institute within NIH	Conquest of Cancer Agency (independent within NIH but insured coordination with NIH)	National Cancer Attack Program within NIH
Status of the NIH	Agency within DHEW	No change (except Cancer Agency "independent" and includes NCI)	No change
Cancer Director Reports to the:	Director, NIH	President	Director, NIH, but see budget and report
Funding Authorization; Budget	Open-ended under present PHS Act	Such sums as necessary; budget submitted directly to President	FY 1972 - $400 million FY 1973 - $500 million FY 1974 - $600 million Sums appropriated to remain available until expended; budget submitted with NIH and HEW and Council comments directly to President. President to request without delay additional appropriation required to pursue development in national cancer attack program or in heart disease and stroke programs.
Construction Authorization	Under present PHS Act (expired 6-30-71)	Such construction as necessary by Director of Conquest of Cancer Agency	Such construction as necessary (Director, NIH, authorization for cancer, heart, and stroke centers)

ISSUE	EXISTING ORGANIZATION	S. 1828 (AS PASSED BY SENATE)	H.R. 10681 (Rogers, 9-15-71
Contract Authorities	Available under present PHS Act	Contracts, leases, etc., as necessary, and grants	Same, except all Institute Directors may approve grants of $20,000 or less without Advisory Council review (initial review group approval still required)
Services and Facilities from Other Agencies	No authority (NASA has this authority)	Director of CCA utilizes with consent the services and facilities of other agencies	Director of NIH utilizes with consent for all NIH research programs the services and facilities of other agencies
Supergrade Level Positions	Under present PHS Act (not less than 115 in NIH under CSC Regulations)	50 (excepted from CSC Regulations) (appointed by Agency Director) (in addition to presently authorized)	Similar to S. 1828 as passed, but appointed by NIH Director for NIH
Special Recruitment of Scientific and Professional Personnel	no authority	May recruit at two grades above normal entry level	Same as S. 1828
Grade Level of Cancer Director	Director, NIH--Level IV. Director, NCI--Asst. Surgeon General, PHS Corps.	Director, Cancer Agency--Level IV. Deputy Director--Level V. Director, NIH, unchanged.	Director, NCI, NHLI, and NINDS--Level IV. also designated Assoc. Directors, NIH. Director, NIH--Level III. Deputy Directors, NIH--Level IV. ASHSA--Level III. Under Sec. HEW--Level II.

ISSUE	EXISTING ORGANIZATION	S. 1828 (AS PASSED BY SENATE)	H.R. 10681 (Rogers, 9-15-71)
Advisory Council	Under present PHS Act	National Cancer Advisory Board supersedes Cancer Council (Director, NIH, is a member), Sec. of HEW, Director of OST, and Director, Cancer Agency, ex officio members.	No new Board, but existing NACC given many of the functions proposed by S. 1828 for NCA Board including opportunity to comment on budget. N.B. NCI Director may call special meetings of NACC.
Peer Review of Grants, Contracts, etc.	Advisory Councils review	Director and Board will insure scientific peer review, either present NIH or new groups.	Director, NCI, will provide for scientific peer review, either present NIH or new groups with approval of Cancer Council and NIH Director. Directors of Institutes may approve grants up to $20,000 without Advisory Council review.
Reports	No cancer report outside of normal appropriation presentation	1. Cancer Agency annual report to President. 2. Board annual report on progress of Cancer Agency.	1. Cancer Program annual report to President and a plan for the program during the next 5 years. 2. President's report to Congress after one year of administrative review of cancer program processes.
Cancer Centers		Strengthen existing cancer centers and establish new ones.	Same, but only as NIH Director determines to be appropriate.

TAB 20

#681

OPENING DISCUSSION - Sloan Management Seminar

As I discuss the view as seen from the chair of management at the National Institutes of Health I will be speaking of a wide angle panorama.

The uniqueness of NIH makes its administration an interesting challenge, and I hope you will find interesting a subjective view; that is, how it looks to me.

The NIH is a consortium, a confederation and yet it is a single agency of Government.

The Bethesda reservation is the headquarters and principal site. There, about eleven thousand persons pursue a great diversity of activities. More than two thousand of them are scientists. They work within nine Institutes, a Bureau, a National Library, a Clinical Center and a number of Divisions, each unit having a relatively high degree of organizational automony. We have one off-campus Institute.

"Intramural NIH" resembles a university, and the philosophy of management which has evolved resembles more than anything else that of the administration of a large university, but without students or football.

However, in prosecuting its research mission, the NIH's major involvement is world-wide. From eighty to ninety percent

of our research budget is spent in extramural settings, mostly in medical schools, universities, hospitals and laboratories in the United States. In this sense we are the principal in a widespread consortium. The management of our extramural research program must deal with a set of givens which differs greatly from those pertaining to intramural activities, and brings us face-to face with the deepest philosophical problems of biomedical science.

Another large component of our work is to encourage and facilitate support in the education of health manpower through the Bureau of Health Manpower Education. This activity also brings us into close relationship of another sort with institutions of higher learning.

The world's largest biomedical library, the National Library of Medicine, is a component of the NIH, and brings with it the challenge of innovation in better methods of access and communication. The Bureau and the Library each in different ways occupy individual arcs of the NIH Director's panorama.

I will not attempt to describe each part of the scene, but will select some areas for closer examination.

Intramural Research

I see as one of the imperatives of intramural NIH the care and feeding of scientists--since they are at the scene of the action. Let me elaborate a bit and for a purpose.

The faculty in a university, and the scientists in a research institution are the essence and strength of the institution. The role of administration in this kind of setting only faintly resembles "governance." The administrator must make <u>some</u> decisions--but he is circumscribed, hedged about on all sides by lesser hierarchies whose consent must be courted. On this subject, Jacques Barzun observed, "When one looks for 'the administration' at a given university one must knock at almost every other door."..."It is not to say that nothing <u>may</u> be done without consent; it is that without consent nothing <u>can</u> be done."

I have reiterated a familiar management configuration to emphasize a special aspect of the NIH Directorship. While the university, with its diffuse and low-key upper administration usually stands operationally alone, the NIH is but one agency surrounded by other agencies charged with direct service missions and having relatively clear-cut lines of authority. The line executives in the superstructure above the NIH thus deal with units in which winning the consent of the governed is not quite as crucial as at NIH.

The Director of NIH is at an interface across which the gradient of command authority is high.

The fact imposes on the Director a special and constant need to communicate up and down. Upward, to secure and maintain

as well as possible the support and insulation for the creative scientist which will allow him to work at his own pace, undisturb This protection is not part of a humanitarian "be-kind-to-scientis movement," but is pragmatic, an essential condition to maximum productivity. At the same time, it is obvious that the Director must communicate a special kind of leadership to his scientific colleagues in dedication to the basic mission of a special agency supported by public funds for a public purpose.

In an article which appeared in Science in May this year George Pake analyzed the power structure within the American university. He observed, "To a large degree the present dilemma of the university is bound up in the fact that administrators who are expected to bear institutional responsibilities are in positions of weak authority. ..."However, he noted that "a significant power of the university central administration lies in the influence it has in the appointment of deans and to a lesser extent, department heads."

Similarly, at "Intramural NIH" the most direct way in which the Director exercises leadership is through his choice of personnel to head the varied activities for which he is responsib

A Broader View

I have discussed a view of methodology--the administration

of a large organizational entity--but there is another vista, much broader, in which "Intramural NIH" is only the foreground.

The Federal Government is the dominant source of support for biomedical research, and will expend this year two of the three billion dollars to be invested in medical research in this country. More than half of the Federal support will be through NIH / In biomedical research, the Federal Government, with NIH the lead agency, approaches the kind of monopoly position as that of the Atomic Energy Commission over atomic energy; the National Aeronautics and Space Administration over space exploration; the State Department over foreign affairs and even the Department of Defense over military affairs.

This fact has imposed a key responsibility for program concept and balance upon Federal legislators and executives. This responsibility they must exercise while weighing the fundamental issue of the relationship of science to society and the question of how to apply science to solving the urgent problems of mankind.

At some point in such discussions the issue begins to turn on such questions as the appropriate level of national investment, targeted versus non-targeted research, basic versus applied, appropriate systems for the allocation of resources, public accountability, and the overall question of who shall make the decisions: scientists or non-scientists?

I would like to say a few things about my ideas of the basic conditions necessary for science to prosper, because I think this is the key in making determinations about how we manage our programs.

We all know that brilliant and dedicated scientists throughout the ages have overcome adverse environments to make their contribution, and no doubt they will do so in the future. The pursuit of knowledge has become enormously expensive and public decisions have much greater influence on science than they had a hundred years ago. Its pace and direction can be altered by the voter.

The chances for progress will be immensely increased by adequate facilities and support, by maintenance of conditions favoring the freedom of thought which creative minds require, and by clearer public understanding of the relationship of science to society in this 20th Century, and of the nature and limitations of the scientific approach.

Our society is now asking more of science than ever before. The irony is that we are not being asked for more truth, but simply for more solutions to specific problems.

Some of the problems biomedical science is being asked to solve are almost exclusively in the domain of science--for example, delineating the precise relationship of diet to [illegible]

death from myocardial infarction or determining the basic conditions under which low level multiple potentially toxic materials in the environment may adversely affect human health. Other problems may become increasingly science-based challenges in the future, such as some of the particularly troublesome social and behavioral problems, as the social and behavioral sciences continue to mature and develop. Still others may never be the types of problems that lend themselves well to the experimental approach. And here I would include most aspects of the familiar age-old enemies of man--poverty, war, ignorance. Even in the area of disease where the experimental approach has produced such brilliant benefits, many problems are not science based. These would include cancer associated with cigarette smoking where motivation not new knowledge constitutes the problem; some hereditary diseases where it seems unlikely that any methods other than selective exclusion of marriages will be effective; and some aspects of pollution and environmental problems, which depend primarily on social tradeoffs rather than development of new knowledge.

In general, these really serious problems of man have been resistant to drastic political and economic remedies. In contrast, there have been dramatic successes in research and technology, and as a result of these successes there is a growing

demand that science solve the problems of humanity, whether or not the problems have a science base. I would repeat: Biomedical science and its resultant contributions can only prosper if there is proper appreciation of the nature and limitation of the experimental method on the one hand, and the relationship of science to society, on the other.

Two key elements are ever present among many in Federal consideration and in the support of biomedical science. The first is the level of effort, and the second is the issue of targeted versus other research.

Attempts that have been made to arrive at some reasonable estimate of how much of the Nation's resources should go into the support of biomedical research, but I find the most compelling case can be made:

. That a significant component of the Nation's talent in the basic biomedical areas should be supported;

. Secondly, that the distribution of this support should be based on an assessment of quality on a basis of such fairness that it is recognized readily as an open and fair system of distribution.

. Thirdly, and very important, that wide fluctuations, especially downward, should be avoided since they are markedly disruptive.

The general characteristics of the NIH extramural peer review mechanism are relatively constant with high sides and low sides, and about 50% of the projects submitted are deemed scientifically meritorious.

I would submit that an appropriate national research allocation might be to insure that no field receive less than enough to pay somewhere between 50 and 75 percent of the meritorious applications. Beyond that point, a decision might be made to place special emphasis on those regular research grants that fall in the field of public interest, such as cancer, heart, or genetics. A public policy of this character would resolve a major continuing concern and debate especially in the scientific community, and also in the Federal Government.

The question of targeted research is a more profound question and is at the heart of the much publicized cancer issue. On the one hand, intelligent people know that the simple assertion of a desire to solve a complex problem gives no assurance of succe on the other hand, there are clear advantages in science in focussing attention on specific problems.

Targeted research programs originate when a domain of science reaches a stage of maturity that makes possible consensus by experts that two conditions obtain: (1) a specific, concrete

and important objective has been identified whose realization would have a significant impact on an important health problem; (2) and that if materiel and personnel resources are effectively marshalled to pursue the objective, the probability of success is high. In this sense, program means that the participants knowingly participate in an organized and deliberate pursuit of the objective or target. Implicit is the fact that the effort is carefully planned, and on a scale that can foresee needs and define requirements with specificity over several budget cycles. The planning is highly centralized and its execution is monitored, controlled, coordinated and integrated by an overall central focus for governance. As the scale of the program enlarges, more elaborate requirements for rapid communication between participants increase and the central point of governance tends to act as a switching station. The plan includes the specification of subobjectives.

In enterprises of this character, the role of the expert in target selection and in the planning of the effort is central.

The term targeted research program has been used in another sense, that is, a marshalling of resources to attempt to attain an objective that is devoutly and urgently desired--by science and by society--even though that objective is not one whose attainment can be mapped out in detailed terms and with confidence

of success. The moving force is a broadly held conviction that the seriousness of the problem warrants a substantial effort even though the prospects of success are slim.

Some of the important basic attitudes toward targeted research programs would seem to include:

. That targeted programs should not compete with level-of-effort supported research;

. That each targeted program should be justified in detail and added to a reasonably sustained and stable system of research.

. That targeted programs of the type first mentioned, for example, those characterized by the identification of an important objective, attainable in principle and highly likely to succeed in practice if pursued with sufficient resources, should be pushed with vigor by an agency such as NIH.

. Targeted programs of the second type present a difficult problem. There has really never been a test of the proposition that important headway will be made if enough resources are focused sharply on an intractable problem. Even though most scientists are uncomfortable supporting this proposition, there is some evidence--if I read Project Hindsight correctly--to support it. Provided a substantial level of effort

investment has been insured and provided these "targets of hope and aspiration" are recognized for what they are, particularly by the political leadership and by society, my disposition is that the scientific community should be responsible to these expressions of societal desire.

These are some of the thoughts and concerns with which we have been preoccupied. I suppose it could be called the mountain range in our panorama. There are discernable foothills here and there of management challenge which I shall only mention as possible points for further discussion:

. The problem of "the rich get richer and the poor get poorer" in Federal support of institutions. The role of the grant in building institutional quality.

.. The problem of evaluating research output. How to make a quantitative assessment of progress? When is one halfway to an unknown goal?

. The problem of "planning the unplannable."

. The daily problem of "deadline decisions" with insufficient data.

. The interrelationships of research, education, and service.

11/5/71 - S. Shelley

TAB 21

RESPONSIVENESS OF PUBLIC SCIENCE
AGENCIES TO BROAD NEEDS OF SOCIETY

Viewed in historical perspective, the growth of science may be regarded in the main as a response to pressing national needs. This has been particularly manifest over the past two decades, when U.S. research and development expanded about ninefold and medical research at twice that rate, largely through Federal support. The recent leveling and, in some fields, decline in funding, at a time when need, achievement, and research opportunity are maximal, urge critical scrutiny of public policy conditioning the support of science programs.

First, one may inquire into the determinants of what are perceived as needs. There are the obvious public concerns--cardiovascular disease, cancer, mental illness, deterioration of the environment. These felt needs may be strongly "culture bound" (the hydrogen bomb, the space race) or even generated (many proprietary drugs). At times, the need, though real enough, is only recognized initially by the specially informed--physicians, military strategists, engineers, regulatory agencies. In this category are often found the scientists themselves. By and large, the demands for scientific investigation ultimately reflect society's *perception of urgencies*, whether or not there is agreement by scientists or other special groups or all the people.

Public and private agencies--governmental, philanthropic, industrial--enter the picture in recognizing the demand and sponsoring the science to meet it. The executive and legislative branches of government play a key

role. The need is for perception and organization; the task, to mobilize talent and treasure and resources.

But it must be recognized that science has its own internal logic--its own vectors, frontiers, paths of flow. Broadly, it is limited at any time by the "state of the art," and can best be responsive to demand along circumscribed avenues. Science programs, to be productive, must be responsive to these exigencies. Among the program responsibilities are accurate assessment of scientific opportunities, concern for the viability of institutions, and development of manpower. The nature of supportive resources should be largely determined by the scientists themselves.

The general public is uninformed in the ways of science. It is the role of responsible leadership to wed the social and the scientific needs. Thus the science agency, standing between the investigator and the people's representatives, must play the part of modulator, planner and leader. Above all, it must provide and sustain the environment in which science can advance.

It should be emphasized that science is not an ivory tower pursuit so long as substantial public funds are required to maintain it in a vigorous and productive state. Principal programs must be highly responsive to public demand--must meet the test of "relevance." Moreover, they must be politically acceptable, must retain public confidence, and must deliver on claims.

With a deepening public awareness of the potential of science to transform our world and our lives, there has come a critical concern for the aims, the cost, and the broader consequences of science programs. Public policy must increasingly take these concerns into account. There will be

no dearth of support for programs that reflect the public demand and are sensitive to the broader human interests.

Mounting concern with the problems stemming from environmental deterioration and population growth aptly illustrates this point. The public requires no prodding today to endorse long-term commitments to research in these areas. A consensus exists, and is reflected in the creation of a national agency to deal with environmental abuse and neglect. The related problem of population growth is also beginning to receive attention and support.

An encouraging trend toward general support of the scientific community--its institutions, resources and manpower--has emerged in recent years. The Congress now accepts the fact that research can flourish only if the institutions conducting it are adequately sustained and the manpower to secure its future adequately prepared. In short, there has been a mounting appreciation of the coordinate nature of the scientific enterprise and of the critical role of publicly supported science in a free society.

Public policy, vested in government and civic leadership, must not permit the dissolution of this emerging trend through insensitivity to public attitudes. The rapid growth of science in the postwar period should not obscure the fact that public acceptance rests ultimately on the belief that the national welfare is being served. Science is not supported for abstract purposes. Unless the citizenry understands why new knowledge is needed and how the Nation benefits from its application, the support of science will be jeopardized. Unless the scientific community responds to the citizenry, it will lose the public confidence it enjoys and requires.

TAB 22

3695

HEALTH MANPOWER EDUCATION LEGISLATION AND HOSPITALS

Robert Q. Marston, M.D.
Director
National Institutes of Health

It is a special pleasure to speak to you on the recently enacted health manpower education legislation. The National Institutes of Health is a member of this association and has worked with it over the years.

The new health manpower legislation--The Comprehensive Health Manpower Training Act and the Nurse Training Act--became law last November 18th. In signing these measures, the President described them as "the most comprehensive health manpower legislation in the Nation's history." These programs represent a significant attempt to grapple with health manpower problems, a basic step in improving health care in this country.

Hospitals actively sought passage of the new health manpower training legislation. A number of the major features of the legislation affect hospitals.

The major themes of the legislation are quite simple--that is to help our institutions produce greater numbers of well-trained and highly qualified health professionals while strengthening the financial footing on which these schools operate. Along with this is an attempt to improve the distribution--by specialty and geography--of the needed health manpower and to attract and retain in medicine and the other major health professions increasing numbers of disadvantaged young people.

Delivered at the 31st Annual Conference of the Maryland-District of Columbia-Delaware Hospital Association, Washington Hilton Hotel, Washington, D.C., January 11, 1972.

The primary responsibility for implementing these laws during the three fiscal years they will be in force--1972 through 1974--rests with the Bureau of Health Manpower Education, a component of the National Institutes of Health.

A section of the Comprehensive Health Manpower Training Act in which hospitals will be especially interested provides for training in family medicine by grants to hospitals. Family medicine is supported in an effort to alleviate the maldistribution of physicians by specialty. Any public or private nonprofit hospital with an approved program of family medicine is eligible to apply. An approved program must include a model family practice unit, which resembles the office of a group of practicing physicians.

Congress has appropriated more than $5 million for training in family medicine in the current fiscal year, and we expect to be able to award 14 grants for about 300 trainees.

Since the elevation of family practice to a specialty in 1969, about 74 residency programs have been approved. Almost 600 residents are currently being trained in approved programs. Many hospitals with so-called general practice residencies are converting to the newer concept of family practice residencies.

If projections are attained, several thousand are expected to be training in family practice residencies in a few years. This legislation should certainly help to meet this goal.

A major effort to improve the geographic distribution of health personnel will be made through Health Manpower Education Initiative Awards. This section of the new legislation authorizes the establishment of Health Training Networks in underserved areas. Congress has appropriated $20 million for these initiative awards in the current fiscal year and more than half of this money will go for Health Training Networks. Administration of the Health Training Network program will be the responsibility of the Bureau of Health Manpower Education working with the Regional Medical Programs Service of the Health Services and Mental Health Administration.

H.E.W. Secretary Richardson has said that these centers or networks offer an important opportunity for improving the distribution of health personnel and for relating health manpower more directly to the changing patterns of health care. Establishing a health training program in a community, we believe, will help raise the entire range and quality of health services available to the community. At the same time, there will be an increased opportunity for education and training of able young people for careers in health care. Add to this the increased likelihood that students trained in the community will be motivated to remain there to practice, and add to this the opportunity provided for continuing education for health practitioners in the area, and you can see why we are enthusiastic about this health training idea.

Officials of the Bureau of Health Manpower Education have visited many localities--including Wilmington, Delaware--and interviewed a number of officials in preparing tentative criteria and identifying likely forms which this program might take.

From what we have learned, it seems that we would do best to view a center or network as a system or arrangement rather than a place--a system that links health service organizations and educational institutions in a way that serves the student, the practitioner and the surrounding community.

A network's educational programs would include residencies, clinical instruction for medical students who would study there on a rotating basis, clinical training for students in allied health programs, and continuing education for health personnel in the vicinity.

Establishing residencies in primary care also will be a major function of this new program. Facilities already in the area would be used to the greatest extent possible. As a result of their new activities, the facilities could provide outpatient and inpatient medical services and could also serve as a referral center for other patient care facilities in the area. Still another important function would be to assist in manpower planning and the development of health care delivery systems.

We plan to enter into contracts with agencies, institutions, organizations or consortia which have established linkages or are capable of establishing linkages between educational institutions and institutions providing medical services. The recipients would undertake the training needed in the area.

Hospitals in rural areas may play a key role in this program by training medical students as well as residents in community settings.

The organization or entity which assumes the responsibility for developing the arrangement will be designated as the lead agency and will be the recipient of the contract. The lead agency will then subcontract with the other participants in carrying out the program.

This is just the birth of this network to educate health manpower, and obviously it isn't going to grow to its full size in just one year. Already some 70 agencies, organizations and institutions--including a number of hospitals--have expressed their interest to the Bureau to participate in the program. In making awards, priority will be given to underserved rural and inner city areas.

By the end of the current fiscal year, we hope to have funded the planning and development of the first training network programs.

Health Manpower Education Initiative Awards also provide us with a means of developing programs to increase the representation of minorities in the health careers. In the past this problem has been attacked under general authorities. The new legislation highlights this issue and gives specific authority for dealing with it more effectively.

The section pertaining to minority group members will be administered by the newly formed Office of Health Manpower Opportunity. This Office within the Bureau of Health Manpower Education focuses on five groups: blacks, American Indians, Spanish-surnamed Americans, women and students. It will provide leadership to identify disadvantaged young people with potential for health careers, assist them in enrolling in health professions schools, and enable schools to offer special assistance to increase their chances of success.

And, I might add here, this is to be accomplished without lowering the standards of an institution. These programs are intended to make up for a particular deficiency in a course area, which became apparent after admission, or to assist in social adjustment problems.

At least $5 million will be available in the current fiscal year for this new effort. Public or nonprofit private health or educational entities may apply for grants under this program.

The new legislation has several devices to increase health manpower in underserved areas.

The Office of Health Manpower Opportunity may award grants to increase the enrollment in health training courses of persons likely to practice in such areas. Under another section of the new legislation, a health professions student may obtain forgiveness of up to 85 percent of any loan for professional studies if he practices three years in a shortage area.

Initiative awards also will be made to train more physician assistants for work in primary care settings. We hope to support some existing programs, start six new ones and plan four (4) others.

The Comprehensive Health Manpower Training Act has replaced institutional grants to health professions schools with capitation grants, raising the Federal funding floor under these schools to a record level. To receive a capitation grant, a school must expand its enrollment. Expansion beyond mandatory increases is rewarded with bonus payments. Schools also are encouraged to shorten the professional curriculum to three years.

New schools may receive added incentives to help them get started in the year preceding the enrollment of the first class and during the first three years of operation. Special grants are available to two-year medical schools which convert to degree-granting programs.

All of these grants are designed to give schools flexibility in using funds in the way they feel will best meet the needs of their institutions. They should help schools increase production of professionals needed in the years ahead.

The new legislation combines the approach of construction grants with guaranteed loans and interest subsidies. It does not eliminate any current authority but expands the funding methods available to include other means of financing contruction for private schools. We expect to help schools generate a combination of Federal and private construction money that will be significantly above the level of our previous construction grant program.

Supplementing the formula grant method of financial support is a continuation of special project authority, including authority for both grants and contracts. This mechanism allows us to help institutions according to their own specialized needs while permitting us to target assistance to those institutions and educational programs that relate most to national health manpower needs.

The Congress has provided separate authority for special project grants to schools in financial distress. This separate authority will be extremely useful in helping those institutions that need additional help in spite of increased support through capitation.

Schools which apply for this help will have to disclose their financial records, indicating the causes of their financial distress, so that appropriate reforms may be devised which they will be expected to put into effect.

The authorization for this financial distress aid is set up so that this kind of assistance decreases as the increased formula aid and other financial resources enable schools to become self-sufficient.

Still another innovation authorizes a program for the development of demonstration and training projects in applying computer technology to the health sciences. The grants will permit demonstrations to adapt the use of computer-based technology by the physician and other health personnel in the provision of health services and to determine what functions performed by a physician can appropriately be performed by other health personnel.

The Nurse Training Act of 1971 strengthens programs for improving and expanding the training of nurses to meet the Nation's chronic nurse shortages.

Support will go to schools of nursing primarily through capitation grants, special project grants and contracts and grants to schools in financial distress.

The special projects provide the impetus and the funds for schools to initiate new programs and methods to improve the quality of nursing and increase the number of nurses available.

During this fiscal year, we shall give special emphasis to the training of new types and levels of nursing personnel, particularly those programs that prepare nurses to assume more responsibilities in primary care. We shall provide support to train more nurses who can

augment physician's services and assist the physician in providing more comprehensive care to larger numbers of people.

We plan to support approximately 225 projects including 40 for training pediatric nurse practitioners and expanded-function nurse practitioners during this fiscal year.

As with the health professions schools, there are provisions for grants to help meet operational costs for schools of nursing in serious financial difficulties. These financial distress grants will decrease each year as the finances of these schools stabilize. We expect to assist about 50 schools this year.

The program for matching construction grants, interest subsidies, and loan guarantees for schools of nursing will permit us to help new or expanding schools provide 530 first-year places and maintain 1,600 existing places.

A program of educational grants and contracts will help us broaden the recruitment of nursing students by identifying potential candidates and encouraging them to undertake nurse training. This program will try to identify candidates who are disadvantaged or who ordinarily would not consider careers in nursing.

The new health manpower education acts have been hailed as landmark legislation. The Federal Government has been given an unprecedented role in the training of health professionals. The varied approaches in the new legislation give us better tools to attack health manpower problems. Record appropriations indicate that some of these tools will be used well.

The Federal Government has NOT assumed this enlarged role of its own choosing. It has been thrust into this situation in response to pleas for action from individuals and institutions throughout the country. Hospitals, for example, have urged Federal action to prevent the closing of additional schools of nursing.

Federal support, regardless of its extent, cannot alone remedy shortcomings that have arisen over scores of years. The main burden rests, now as in the past, with the non-Federal sectors of the health industry. But working in close cooperation we can raise the level of health care for citizens everywhere.

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TAB 23

#676

THE BACKGROUND OF THE NIH POSITION ON ETHICAL PROBLEMS OF CLINICAL STUDIES*

Robert Q. Marston, M.D.
Director
National Institutes of Health
U.S. Department of Health,
Education, and Welfare

There is considerable evidence of growing public interest in the ethical problems of clinical studies in the human. Such mounting interest is an inevitable consequence of increasing general awareness of the new dimensions in scientific capability: capability to intervene in biological processes which until recent years have been beyond our understanding.

- Recent widely publicized national forums have focused on the ethical problems of research;
- The Senate has adopted a measure which would establish a National Advisory Commission on Health Science and Society to study the ethical social and legal implications of advances in biomedical research and technology;
- An important Senate Committee has begun hearings for the announced purpose of determining specific policies and legislative proposals to deal with the ethical problems related to human clinical studies.

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*To be presented at the 28th Annual Meeting of the American Fertility Society--Symposium: "Clinical Studies in the Human: The Ethical and Scientific Problems," on February 28, 1972 In New York City.

I view this Forum as timely and am particularly pleased to have this opportunity to provide background on the policies of the National Institutes of Health and to describe our practices with regard to clinical research.

The policy of the National Institutes of Health on the ethical conduct of clinical studies is definitively stated in procedures which are designed to assure:

- protection of the rights and welfare of the subject;
- weighing of the risks against the benefits, and
- determination that informed consent is to be obtained by methods that are adequate and appropriate.

However, instead of attempting to provide a rigid catechism of substantive "dos" and "don'ts," we depend primarily on the collective judgment of groups of competent and reasonable advisors, and upon responsible review at the scene of the research on a protocol by protocol basis.

In our intramural research, such judgment and review is the responsibility of our Medical Board. In our grant and award programs, our initial review groups, including the familiar Study Sections, and the several National Advisory Council assist in making the final judgments.

In recent years we have required extramural grantees and contractors to establish their own institutional review groups both to review and endorse proposals as ethically sound before they are made to NIH, and to provide for continuing review of the projects after the fact of award. Since this is the aspect of the NIH policy most familiar to the public, it is frequently referred to as "the" NIH policy. However, there is a long history of concern on the part of NIH Study Sections and Councils with ethical questions beginning in 1946, and with the NIH Clinical Center policy which came into being simultaneously with the Center itself in 1953.

The extramural aspects of NIH policy--those requiring institutional review of grant applications--affect the largest number of institutions, scientists, and patient-subjects. Accordingly, I will limit my remarks largely to these.

The NIH method for assuring the protection of subjects in clinical research has remained essentially unchanged since 1964. Primary responsibility for safeguarding the rights and welfare of subjects involved in an NIH-supported research project necessarily lies with the grantee institution. Since the investigator and his institution are together legally accountable for any injuries that might result from the conduct of the project, control should logically

stay with the institution. Further, the project, which was conceived by the principal investigator, must remain his to direct. He must be free to alter his methodology and approach if such changes help him reach his goal.

However, though the initial protocol is carefully reviewed in the NIH approval process, it is not practical to require the same kind of review for interim changes. Our advisors cannot repeatedly be assembled in Bethesda to deal with problems as they occur, nor can decisions on these problems be delayed until the regular meetings of these groups.

We have concluded that legally and practically the immediate decision-making authority should remain with the grantee institution. Such a position is based on the conviction that supervisory practices of grantee institutions are adequate to the task. Though this undoubtedly was the case in 1963, a study published that year showed that only two of 86 medical schools had taken any <u>formal</u> institution-wide steps to insure reviews of clinical research activities. In response, my predecessor, Dr. James A. Shannon asked what is now our Division of Research Resources to study the problem and recommend a suitable set of controls. The report of the Division restated the issues in words generally descriptive of the problem as we see it now almost a decade later:

- Historically progressive changes in the kinds of clinical research which it is possible to undertake are changing the

nature of risks and values relating to clinical research.

- There is no generally accepted professional code relating to the conduct of clinical research.
- The legal status of clinical research is ambiguous.
- The NIH supports clinical research in a wide variety of research institutions and hospitals. There exist conspicuous differences in institutional attitudes toward acceptable professional conduct of clinical research.
- As the number of investigators, subjects and institutions engaged in clinical research increases and as the nature of the risks ventured changes according to the extension of research into new areas, a mounting concern is expressed over the possibility of untoward events.

The committee concluded that the NIH was not in a position to shape the foundation of medical ethics, to design a code, or to assume an exclusive or authoritarian position concerning the ethical boundaries of clinical research. These conclusions still seem valid.

A decision was subsequently made by Dr. Shannon and by the Surgeon General to bring the matter before the National Advisory Health Council. The Council's recommendation, formally adopted on December 3, 1965, constituted the core of the Public Health Service

policy issued in 1966 and 1969, and of the DHEW policy issued in 1971. The present wording reemphasizes the grantee's basic responsibilities for safeguarding the subjects' rights and welfare and then continues:

- "In order to provide for the adequate discharge of this institutional responsibility, it is the policy of the Department that no grant or contract for an activity involving human subjects shall be made unless the application for such support has been reviewed and approved by an appropriate institutional committee.
- This review shall determine that the rights and welfare of the subjects involved are adequately protected, that the risks to an individual are outweighed by the potential benefits to him or by the importance of the knowledge to be gained, and that informed consent is to be obtained by methods that are adequate and appropriate.
- In addition, the committee must establish a basis for continuing review of the activity in keeping with these determinations.
- The institution must submit to the DHEW, for its review, approval, and official acceptance, an assurance of its compliance with this policy."

To date more than 750 institutions, including all major NIH grantees and contractors, have filed general assurances of compliance with DHEW policy. These assurances

- Identify the statement of principles or code which the institution will use to guide its reviewers;
- Describe the committee or committees that will carry out the review;
- Describe the procedures which the committee will follow in carrying out its review responsibilities;
- Describe the procedures which the committee and the institution will follow to provide administrative overview of their operations.

The statement of principles relied upon by the great majority of clinically oriented institutions is the Declaration of Helsinki of the World Medical Association. The ethical principles set forth in the Declaration have been formally endorsed by the American Medical Association and eight of its component research groups. It is probably the nearest thing to a universal ethical code presently in existence. Some few institutions rely on the older Nurenberg Code, others on the British Medical Research Council's statement on Responsibility in Investigations on Human Subjects and, in a few instances, on a code which is the peculiar property of the particular hospital or school.

Committee structures vary widely. DHEW policy does not specify size or membership. The policy places strong emphasis on the need for breadth of review. It emphasizes that the committee should have the professional competence not only to review clinical projects, but also to determine acceptability of the project in terms of institutional regulations, applicable laws, local standards of professional practice and community attitudes. NIH review groups can provide in-depth scientific review, but they cannot provide the breadth of review possible in a Medical Center, which can assemble a committee representing the full spectrum of medical disciplines, as well as "lay" representatives from medical administration, legal medicine, and from the surrounding community.

Recently the Food and Drug Administration issued its own peer review requirements paralleling the DHEW policy which governs NIH clinical research. The only significant difference is that it has made lay membership on institutional review committees a "must," rather than a "should." I suspect that any future amendments to the DHEW policy will include a similar change.

Our guidelines provide a high degree of flexibility for the institution in establishing its review procedures, but we insist that a responsible committee be established and that the committee adhere strictly to the three basic criteria I have already mentioned.

- Protection of the rights and welfare of the subjects
- Weighing of risks against benefits

- Determination that informed consent is to be obtained by methods that are adequate and appropriate.

It seems obvious that the first two criteria are most critical to the ultimate decision of any review group. Whether or not consent is in fact informed, admittedly, is difficult to assess. We oftentimes are in an uncertain situation in which inadequate information, communication problems, and the inability of the subject to comprehend--or to read--or to listen-- can be easily confused.

There is no clear-cut statute to guide us. In a frequently quoted Kansas case, the court said:

- "The duty of the physician to disclose...is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances. How the physician may best discharge his obligation to the patient in this difficult situation involves primarily a question of medical judgment."

The court did not state what else is involved. We would argue that in many instances psychological judgment, sociological judgment and, at the grass-roots level, community judgment, may be equally important.

Within the NIH itself we have, within recent weeks, come face to face with a deep well of minority sensitivity to what was thought

to be majority controlled research, even though it involved no more physical injury than that required in the removal of 10 millilitres of blood. Their concern was with what is termed the "hidden agenda" or the "hidden protocol," the possibility that that 10 ml of blood can be used for informational purposes potentially damaging to the donor. To some subjects, double-blind techniques, placebo studies, or even random assignment procedures can carry a suggestion of selection and deliberate deceit. Such misunderstandings point up the sociological overtones and are reminders that we are not dealing with narrowly limited scientific and legal questions when we confront the ethical problems of clinical research.

In the chain of events stretching from an initial biomedical research concept to the ultimate delivery of improved medical services the most critical link often is the human research subject. If through lack of care or excess of zeal we allow abuse of the human subject we fail ourselves as professionals and endanger the beneficial forward march of research.

Has the NIH policy been successful? We believe it has. The applications involving questionable procedures--never many--have become noticeably fewer in the past six years. However, we still interpose our judgment by disapproving applications (about 1¼%) because of hazards, and we know that as new methods are learned, new insights are gained and tested, we will face agonizingly difficult decisions.

Finally, is there any particular concentration of problems in areas of interest to the American Fertility Society? I think that the answer is yes, though we would be hard put to document it. In vivo conception and gestation, cloning and "genetic engineering" have become moral and ethical battlegrounds while still in their biological infancy. Fetal research is another area of controversy, though little practiced. Amniocentesis is among the techniques contributing to the high frequency of questions and disapprovals involving biopsy. Umbilical catheterization for research purposes is a frequently questioned procedure.

All pediatric research raises questions as to the right of the parent to consent to the child's involvement in research, particularly if the research confers no direct benefit on the child. The view of the United States courts seems to be that while parents may make risk judgments for themselves they have no right to sacrifice the rights of their children. Nevertheless there seems to be a general consensus that research involving negligible risk to the child should be accepted in the interest of gaining new knowledge about the problems of all children.

I believe that the issues we are to face will require the best thinking of clinical researchers, medical practitioners, the legal profession, ethicists, sociologists, all working in concert, not in isolation. If such solutions are not so arrived at they are likely

to be reached in the heat of adversary debate in the courts, or in legislative actions. If such decisions tend to lock medicine, ethics, and law into a fixed pattern, the results may not serve the long term interests of society as a whole.

These problems can be effectively attacked, though not necessarily solved, by discussion--public discussion, professional discussion, organized discussion, within those organizations specifically concerned with biomedical science and public policy, and, most critically, by broadly based groups within the research institutions themselves. Today's discussion is a good example.

TAB 24

#684

INAUGURAL REMARKS*

BY

Robert Q. Marston, M. D.

It gives me a great deal of pleasure to participate in this Symposium on Viral Hepatitis and Blood Transfusion and to deliver these opening remarks.

Viral hepatitis is one of the most serious infectious diseases affecting the American public today. It is a matter of great concern in public health agencies, clinics, and research laboratories throughout the country. Although hepatitis is a disease which has been recognized for centuries, little progress has been made in determining its etiology.

Volunteer studies in the late 40's and early 50's were stimulated by the enormous increase in hepatitis during the second World War. Two primary types of hepatitis, A and B, were identified and characterized, and a presumed viral etiology for each was ascertained. However, interest and progress in hepatitis research waned after some of the volunteer studies experienced an unacceptably high mortality rate; and the studies were consequently terminated.

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*To be given at the Symposium on Viral Hepatitis and Blood Transfusion at the University of California, San Francisco, March 25, 1972.

But the problem is too serious to be neglected. Moreover, it has been aggravated by the extensive but necessary use of blood transfusions and blood products and by the increased risks attributed to the drug culture.

Transfused blood is estimated to cause more than 30,000 cases of overt hepatitis in 1,500 to 3,000 deaths every year in the U.S. Since there are many subclinical cases of viral hepatitis, the actual incidence has been estimated as high as 150,000 cases annually.

Recent discoveries will reduce the impact of the hepatitis-contaminated blood problem, but will not result in a quick solution of the overall hepatitis problem. The greatest obstacle to development of effective preventive measures is the need to isolate and identify the causative agents, presumably viruses. The whole history of infectious disease research supports the view that once the causative agents can be isolated and grown, developments in diagnosis, treatment and vaccines can be targeted.

Progress in the hepatitis field provides a striking example of the benefits of fundamental research. The discovery of the Hepatitis B antigen is a case history which

underscores the importance of research on a broad scientific base and the need for insuring communication between different scientific disciplines.

You are familiar with the story--how a clue was found in a most unexpected way. A medical geneticist, Dr. Baruch S. Blumberg, who had worked at NIH in the 1960's and continued his investigation as a grantee, headed a scientific team studying blood proteins in primitive peoples of the South Pacific. A previously unidentified protein was detected at the NIH in the blood of an Australian Aborigine. The discovery was crucial, and in time realization of its significance emerged through continued work of the original team, and through the work of a growing number of virologists and other investigators.

Successful exploitation of the discovery like the hepatitis antigen requires the commitment of ever increasing numbers of scientists and of research facilities. The work on the problem proceeded in many laboratories over the nation and in six different components of the NIH.

At one point, a large number offrozen and stored blood samples which had been collected in 1952 for a study in the Division of Biologics Standards was tested. The samples were known to be contaminated with hepatitis agents, and in what

DBS Director Murray called "serologic archeology," the newly discovered antigen was found in almost three-fourths of the specimens.

In the Hepatitis B antigen story, the mutual dependence of targeted and non-targeted research is illustrated.

The importance of an obscure clue was sensed, then verified, and this stimulated a new wave of interest in the scientific community. Hepatitis research burgeoned. Interim research reagents for Hepatitis B antigen were made available by the NIH to investigators to evaluate their test systems for detection of the antigen. With the use of high speed ultra-centrifuges, a group of scientists began extracting Hepatitis B antigen from positive human sera.

Scientists thus had available carefully characterized reagents which permitted more accurate comparisons of research results.

Special publications were initiated by the NIH to facilitate quick and informal exchange of information between scientists and their colleagues around the world.

The promise of significantly decreasing the incidence of post transfusion hepatitis by identifying and eliminating blood which is positive for Hepatitis B antigen became a reality early last year with the final issuance of Federal standards for the antibody to be used in testing for Hepatitis B antigen.

At this time Hepatitis B Antibody is now commercially available from seven federally licensed manufacturers. The current supply of the product is more than adequate to meet the national needs for testing all blood and plasma donors.

Hepatitis B antigen testing has moved from the experimental laboratory to the blood banks with extraordinary rapidity. The development of more sensitive, practical and reproducible tests is under intensive study; within the next few years, other tests--some involving new principles--may be introduced.

Progress is being made with primates as animal models of serum hepatitis in order to gain a better understanding of the disease and ways that it may be prevented or treated.

Published reports of transmission of Hepatitis A to the marmoset, a subhuman primate, offer hope for progress against this human virus.

Several laboratories have reported success in transmitting the virus Hepatitis B to subhuman primates, including chimpanzees and rhesus monkeys. These findings, though not yet published, offer promise for markedly increasing our understanding of the virus of Hepatitis B.

The search for a vaccine is also continuing, and some progress in this direction has recently been reported.

But there are several preliminary steps which must be taken before we can proceed to vaccine development--proving the viral character of hepatitis agents, growing them in animals or tissue culture, finding a safe strain of virus, producing prototype vaccines, and testing them for potency and safety. Despite all the new discoveries, therefore, full control of hepatitis is still very much in the future.

I have already mentioned the necessity for close communication and coordination among a number of scientific disciplines in the field of hepatitis. We have faced this matter squarely at the National Institutes of Health, where at least five of our Institutes and Divisions are engaged in programs related to hepatitis.

The Division of Biologics Standards has the responsibility for establishing and maintaining standards of quality and safety for all biologic products, including human blood for transfusion, products prepared from blood, and the test materials and methods used to assure that products meet standards.

The National Blood Resource Program of the National Heart and Lung Institute is responsible for initiating research on improving

resources and usage. This includes development of new technology to assure safety.

The National Institute of Allergy and Infectious Diseases is charged with research on the causative agents of viral hepatitis, with developing new methods for detecting hepatitis virus, and with vaccine development.

The National Institute of Arthritis and Metabolic Diseases has a general responsibility for research in liver diseases, including clinical diagnosis, medical management and the fundamental processes underlying these diseases.

The Clinical Center, in its use of blood and blood products, is an intrinsic part of our research effort on hepatitis. Also, the broad virologic and immunologic capabilities of the National Cancer Institute are being called on to help solve some of the basic problems involved as well as to assure that new vaccines are free of tumor-inducing viruses.

It is essential that these efforts be coordinated, both in the interest of program efficiency and economy and in order to apply the results of research findings to human health as quickly and expeditiously as possible. Last year, therefore, I established an NIH Task Force on Research on Viral Hepatitis

to coordinate our efforts within the NIH and to mesh this with related work of other agencies. The Task Force also serves as an information exchange in this field.

NIH has also recently sponsored formation of a National Academy of Sciences/National Research Council Committee on Viral Hepatitis. This Committee is assisting in coordinating hepatitis research activities on a national level to assure optimal use of new information and biological materials and to encourage development of a standardized system of terms.

The problem of viral hepatitis, as the title of your Symposium indicates, is closely linked to the need for an adequate and safe supply of blood and blood components for transfusion. Blood services have not kept pace with the Nation's expanding demands for medical care. The President identified this need as a matter of national concern in his Health Message to the Congress earlier this month. He directed the Department of Health, Education, and Welfare to study this problem and recommend a plan "for developing a safe, fast and efficient nationwide blood collection and distribution system."

The problems inherent in developing such a plan are obviously great. In addition to the medical considerations, there are legal, social, and economic factors that must be kept in mind. We will need to draw on the skills of modern management and technology. Above all, however, we will need the input of the medical and research communities. We are making every effort to consider all aspects of the problem and to keep all our policy options open. I invite your serious attention to this problem of national importance.

I hope too that this Symposium will encourage many of you to participate in the search for solutions to the many unanswered questions about viral hepatitis. You are zeroing in on a field of lively interest indeed, one in which the opportunities are great. I feel sure that this Symposium will serve its announced purpose of providing a constructive framework for the cross-fertilization of ideas in the hope of furthering our knowledge and understanding of one of the most serious infectious diseases in this country.

TAB 25

BIOMEDICAL RESEARCH SUPPORT TODAY*

By

Robert Q. Marston, M.D.

Mr. Odom--Members of the American Association of Neurological Surgeons--Guests--Ladies and Gentlemen.

I have chosen today to limit my discussion to the biomedical research programs of the National Institutes of Health. You will recall, however, that since 1968, NIH has been responsible also for programs of the Bureau of Health Manpower Education and the National Library of Medicine.

Also, I shall not speak specifically about neurosurgical support, since that is the subject of a panel discussion later this afternoon.

I do plan during the next half hour or so to discuss the following matters--each of which I believe is important to us all.

First, to acknowledge--appropriately here in Boston and before this group--the debt which the rest of medicine owes to the contributions of those working in the neurosciences. While

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*Cushing Oration given at the 1972 meeting of the American Association of Neurological Surgeons, Boston, Massachusetts, April 18, 1972.

I speak here primarily of substantive contributions of neurophysiology to physiology and of neurosurgery to medicine and surgery generally--let me also note the essential contributions many of you have made to the whole biomedical system of this country.

I'm well aware of this personally through such individuals as Barnes Woodhall who served on my personal advisory committee, Earl Walker who was also a member of a council I personally chaired and many others.

Second, I shall focus on the worldwide debate on how best to serve the needs of a society which is increasingly dependent for its survival on technology and knowledge. One symbol of this broader debate is the question of targeted versus non-targeted biomedical research.

My third point will be the impact of what some consider to be the normal oscillations of Federal support programs--oscillations from which biomedical research was protected for many years because of--the past "sputnik" enthusiasm for science generally--the facts that the sums of money were relatively modest--and because of protection against the decrease side of potential swings by our guardian angels in Congress--Hill and Fogarty.

While I shall not resolve these later two points, I do hope to attract your attention to them.

In his Foreward to "The Life of Sir William Osler" Harvey Cushing begins "Because of Osler's interest in the history of his profession the effort has been made in these volumes to bring him in proper alignment with that most remarkable period of the annals of medicine through which he lived and of which he was part." Cushing was successful in displaying in some detail the movement of medicine, including science, education, and practice, through his examination of the life of one man. In turn John Fulton was able later to achieve much the same result in his life of Cushing whose own career symbolized, perhaps better than Osler's, the sweep of "that most remarkable period in the annals of medicine."

As I was preparing these remarks, I received a reprint of the memoirs of Howard Florey--Nobel Laureate for his work on penicillin. It was my privilege to work with Florey in the late 1940's. The association between Florey and John Fulton, Cushing's biographer, was close, both professionally and personally. Fulton worked with Florey in the 1920's under Sir Charles Sherrington and during World War II the Florey children lived with the Fultons.

The coincidence of receiving the Florey memoirs at a time when my thoughts were turned to Harvey Cushing brought me a warm sense of personal involvement with this occasion through a chain of valued relationships.

It struck me how the lives of these two men, Cushing and Florey, though overlapped in time, symbolized two distinct eras in the history of biomedical science. Cushing died in 1939, only thirty-three years ago. Howard Florey died just four years ago.

I focus on Cushing and Florey--two important personalities in the history of science and medicine--for a specific purpose. They illustrate an important common thread which runs through the history of scientific and medical progress. I could have chosen Lister or Pasteur or Nirenberg or Sutherland or any of a large number of other notable scientists to make the same point. That is, the evidence is clear that in medicine major innovations of significant impact and broad applicability have emerged and continue today to emerge largely as the result of the work of individuals and small groups pursuing ideas arising out of their own experience and reflecting their personal creativity.

That is not to deny that important advances have been achieved through other approaches. The malaria screening programs of World War II, the NCI cancer chemotherapy program, a variety of developmental activities in the pharmaceutical and vaccine area, to name only a few, have resulted in singular achievements through carefully planned, highly-organized broad scale attacks on a specific problem. However, for the most part acquisition of new knowledge and progress in medicine has depended predominantly on the contributions of the creative individual in nurturing environment, often under inspiration from an older scientist of eminence. There is no compelling evidence that this approach will be less effective in the future than it has been in the past, or that any other approach will make a significant difference in the rate of truly important discoveries.

I believe that the preponderant majority of working scientists in this and other countries would agree that the surest course to progress is to provide optimal training and adequate support for the most talented and to give them maximal intellectual and operational freedom.

Some of the greatest advances with the broadest implications have emerged from single minded concentration on the essence of a problem as such-- [illegible] consequences of its solution.

In describing his attitude toward his work on penicillin, Florey made an almost unbelievable statement, "I don't think the idea of helping suffering humanity ever entered our minds."

One senses over-modest understatement here akin to that expressed in Florey's last recorded reference to the subject when he said, "We had a bit of luck with penicillin--a great deal of luck."

Against this highly individualized view of the history of the progress of biomedical science, a view seriously to be considered, what can we say about today's developments at the policy level?

In the spring of 1972, in this country and world-wide we have moved to a considerable degree away from "individual" science as I have described it to a greater dependence upon what has been characterized as programmed or organized or targeted research. Such targeted research is to be distinguished from development or technology, which is yet another process. The search is still a search but it has been programmed and has a strong element of exterior direction.

If one looks abroad, the most common questions of science policy across a wide range of governmental and political forms is not whether but how can basic biomedical research be targeted more effectively on recognized health problems.

I have just returned from the USSR where serious concern was expressed about how effectively and efficiently to carry out national research programs in view of the considerable degree of regional and institutional freedom of choice which exists there.

A year-long debate has been going on in the United Kingdom which in essence relates to the continued autonomy of government-supported science. The arguments for change and for maintaining the status quo are reflected in the Rothschild and Dainton reports and the resolution of these polar positions is expected soon.

In this country, there has been much discussion for many years but the Cancer debate of last year symbolized, more than any other single event, the increasing polarization between centrally organized large-scale targeted research on the one hand and decentralized investigator-initiated research proposals selected for support through a process of peer reviews on the other. You will recall that all who spoke on this problem agreed that there was a need for both, and that the question was one of appropriate balance. The fact of the matter is that during the last few years, the balance

has shifted sharply in favor of targeted research. The aggregate support of biomedical research in this country has increased in a completely unprecedented fashion, even when compared to the rapid increases of the mid-50's and early 60's. The NIH budget for biomedical research in this country grew from less than $90 million in 1946 to a peak in 1967 of over $1 billion. What has not been fully recognized is that after a transient dip in 1970, the NIH budget for the research institutes and divisions has increased about 40 percent in two years to a total of almost $1.5 billion in 1972.

This rapid and significant growth has been concurrent with a new concern for re-ordering priorities, growing consumerism, changing economic relationships internationally and domestically, continuation of the civil rights struggle, and a sense of the urgency of problems of the ghetto, of population, of pollution, and of possible exhaustion of vital resources.

It is inevitable then that biomedical science, now an even larger enterprise, would continue to be a topic of concern for non-scientists and indeed for the political process.

A more compelling basis for its public visibility is the increasingly urgent problem of the delivery of health services to the American people. Such societal pressures, expectations and hopes, predictably have had a significant impact on the ways in which the increased funds have been distributed. Thus, of the 40 percent increase, roughly $400 million, $200 million is invested in cancer, $60 million in cardiovascular and $30 million in population research, earmarked to a greater degree than in the past for expenditure through centrally programmed targeted efforts.

Equally significant as the increased targeting, has been the substantial increase in effort by professional and lay groups to gain additional visibility for the area of their particular interest. Not only has there been pressure for an expanded and autonomous Cancer effort, but there is currently before the Congress a proposal for marked expansion in cardiovascular research. Specific legislative proposals have been introduced to confer Institute status on areas such as Eye--successful in 1969--population, gerontology, gastro-enterology, sickle cell disease, and kidney disease. The basic impetus to achieve separate categorical status is the hope to guarantee future financial support as well as other benefits such as the development of expanded Federal laboratory activity.

My first point was that the history of science and medicine indicates a heavy dependence on investigator and small group-initiated research. My second point is that we have already taken, in this country, significant steps to place a larger proportion of our bets for the future on a new way to doing business: the targeted program approach to research which is more reminiscent of some of the successful programs in the areas of technology and development. The advocates for these two positions have become in some ways more highly polarized than was the case a few years ago. Fortunately, increased support overall has made it possible to accommodate the emphasis on targeted research without serious disruption of investigator-initiated research.

As Director of NIH, I have supported both targeted programs and regular research projects on the grounds of what I believe to be sound philosophy. However, in recognition of the fact that undifferentiated research fares less well in non-scientific decision-making than the highly visible targeted programs, I have swung my weight when possible toward the maintenance of investigator-initiated research projects, and I shall continue to do so in the future.

I would like to turn back now to some questions of balance in order to be quite explicit.

The research programs for which additional funds are requested in our 1973 budget--cancer, arteriosclerosis, lung diseases, sickle cell anemia, and population research--are often referred to as 'special emphasis' programs. While these programs do, indeed, receive special emphasis, each of the Institutes has in addition some half dozen or more areas which it describes as "new initiatives" or "high priority programs" or "special emphasis programs." Apart from the Cancer Institute, which is now a rather special case, the nine other Institutes and the Division of Research Resources (which has comparable programs) have a total of 60 program areas to which they give very special attention--and to which they devote slightly more than half their funds. The total research budget request for the ten Institutes of NIH for 1973 is $1,129 million of which $781 million is earmarked by the Institutes for the 60 program areas that are of special concern to them--either in the light of the special health problems they represent or because of the special opportunities for progress they offer.

These concerns of the Institutes are often overlooked by those who think of the NIH activities mainly in terms of free-ranging research, and who regard the regular research grant as the Federal Government's chosen instrument for supporting medical research in academic institutions and hospitals. Since 1948, NIH has been highly successful in managing a rapidly expanding program in a way that subjected the academic community to a minimum of bureaucratic interference with its conduct of research. Despite the very considerable competence and high repute of its own scientific staff and advisors, the NIH has never thought it appropriate--or, indeed, feasible--to attempt to direct the entire national medical research effort. On the contrary, NIH has always felt that in medical research the maximum freedom for the investigator is a condition for maximum creativity.

The effectiveness of the system is manifest, on the one hand, in the remarkable growth of American capability in the biomedical sciences and, on the other, in the tremendous advances in medical practice and in basic knowledge which that enhanced capability has brought about.

NIH's free-enterprise philosophy and the managerial system that has evolved from it have tended to obscure the

fact that NIH is--and has always been--a mission-oriented agency with quite specific goals that it wishes to achieve. While its central task has been to build and sustain the national capability for medical research, it has always had specific objectives which it sought to attain or projects which it sought to promote.

In so doing we have been increasingly aware that there is no substantive difference in the biomedical field between so-called 'basic' and 'applied' research. It is largely a semantic difference--it is not so much a question of what is done as why it is done. A botanist studying the effect of intermittent artificial light on the growth of plants is doing basic research if his motivation is his interest in the behavior of plants but applied research if his motivation is to increase the yield of his greenhouse--his results will be the same and so will their usefulness to nurserymen. It is also often a question of timing: what is 'basic' yesterday may be 'applied' today. Abstruce work in 'solid state' physics in the 1940's that was of no interest to anyone but other 'solid state' physicists, made possible the transistor radios and computers of the 1950's and the space flight of this week. Similarly, the esoteric research on the molecular structure of ribonucleic acid and deoxyribonucleic acid of the past two decades [illegible]

resulted in a gigantic leap forward in our understanding of heredity, has set the science of genetics on a new course, and is now setting the stage for dramatic changes in the management of a variety of medical problems during the next two or three decades.

For example, the development of an effective and reliable influenza vaccine has been frustrated by genetic shifts in the virus. Furthermore, viruses obtained from patients are unsuitable for growing in chick embryos, as is necessary for vaccine production. As a result, there is no certainty that a vaccine will be available when the next major outbreak of influenza, expected in the mid-1970's occurs. However, the new techniques of genetic engineering may make it possible to hybridize the new virus to adapt it to propagation in chick-embryo and accelerate its growth so that a usable culture can be obtained in two weeks--instead of 2 or 3 months. Experiments are also underway for hybidridizing a virus to inhibit its growth at the higher temperatures that prevail deep down in the respiratory tract in order to limit its effect to a transient infection of the upper respiratory tract. Each of these effects--egg adaptation and temperature sensitivity is controlled by a single gene--which can be introduced rapidly

into new strains of influenza viruses. While the success of such genetic engineering to produce a vaccine-control influenza must await further testing, ten years ago such a project would have seemed almost as fantastic as sending a man to the moon.

Patterns of research such as these on which the solution of so many of our health problems must depend, cannot be foreseen. They clearly cannot be planned or organized. It will therefore remain true, for many decades to come, that progress against the broad spectrum of diseases will come from research on the unsolved problems in the basic biological sciences. How to pursue the answers to these problems must be left to the collective wisdom of the scientists engaged in the various fields. We can best accelerate the research by making it possible for more bright young men and young women to undertake it, by making the necessary facilities available to them, and by giving them free rein to their intellectual curiosity and inspirations.

Few perhaps would disagree with anything that I have said so far, other than perhaps to quibble with my obvious bias in favor of a long- and medium-term research rather than a short-term, more targeted or directed research. All agree that we should have both, and all agree so far as I can tell

that we need further debate on how to strike just the right balance. And even that debate is not very keen when budgets are rising, or at worst, remaining reasonably stationary across the board.

There are profound differences when one assumes, as all of us must begin to accept, I think, the inevitability of having to work within fixed resource limits. For instance, Secretary Richardson has emphasized that it is simply not possible to do all the potentially worthwhile things that could be done in the domestic area for the people of this country. For example, he has asked the question in the health area, "What would it take in human and physical resources to bring the health care of the entire population up, to say, that now being received by the people in the upper third of the social-economic strata of this nation?" While I have not seen the results of this analysis yet, I strongly suspect that there will emerge in some areas, at least, essentially impossible resource constraints.

Looking only at biomedical research, while I hope that we do not repeat the decline in growth and ultimate decrease which characterized the late 60's through 1970, I do not for the moment believe that we shall continue to have a 40 percent

increase every two years indefinitely. It is against this background of the presumed inevitability of resource constraints that many speak to the urgency of the current situation compared to previous periods of history. Thus, they ask, "Do we have time to afford other than a crash program in population research in view of the urgency of the problems of unlimited growth brought out so well by the Club of Rome recently?" Or, "Will society tolerate growth or maintenance in long-term investments in health research in view of existing solvable immediate problems of crisis proportion in the application of the knowledge we have today?"

Thus, in many ways, the spring of 1972 may be one of our more comfortable periods as far as reasonable accommodation between the provision of conditions for effective support of biomedical science in this country, particularly as it applies to the balance between nationally targeted vs. investigator-initiated research. But suppose with me, for a moment, that we were to face a situation similar to the expenditure control restraints of 1967. Would the targeted programs be excluded from such constraints, or even in fact continue to grow at the expense of the goose that really lays the golden eggs?

In the case of a serious financial constraint, one could envision a situation in which the advantage would lie totally with short-term, highly visible, publicly appealing targeted programs. Under such conditions the question goes further than an academic discussion of proper balance. Indeed, the unpredictable oscillations in research funding experienced during the late 60's seriously threatened the whole national system for biomedical research so painstakingly put together during the preceding two decades. Large numbers of grant applications rated as highly meritorious and almost indistinguishabl in quality from those awarded remained unfunded. Included in the unsuccessful applications were many first ventures from young investigators who proposed to embark on research careers. Federal administrators were forced to reduce moral commitments by actions which seemed to be not only artitrary but also to denigrate the judgments reached in the peer review process. The competition became so keen that many investigative teams which had worked together for long periods of time were fragmented. Finally, the success of a competing renewal application was sometimes more dependent on fortuitous timing of review than on its absolute scientific or program priority.

These events sorely tested the system. If in the future fiscal restraints should be coupled with sequestration of funds for targeted areas, the investigator-initiated research grant programs of NIH would be dealt a severe blow. Thus, it is wise during this relatively quiet time for all of us to think seriously about how best to meet national needs and assure the maintenance of the quality of research, as well as focusing on the needs of one's own special field.

In facing such basic problems as the question of relative investment in long-term vs. short-term goals there is need for men like the one honored today.

Dr. Cushing's trained, restless, probing mind--his ability to attract and inspire his associates to the pursuit of excellence--these are the indispensable qualities. No matter how research is organized, its forward movement will depend ultimately on men who possess these qualities.

As I said at the beginning, the world has changed since Cushing's time--so much so that in a recent excellent article in Science by Harvey Brooks, entitled, "Can Science Survive in the Modern Age?", he quotes Caryl Haskins: "Only a cultural climate where the fundamental drives of curiosity and the love of discovery for its own sake are understood and cultivated can a true science flourish." And then he says, "One [illegible]

the questions I would like to raise in this article is 'Whether in fact the conditions of modern society are generating a cultural climate which is no longer hospitable to the cultivation of a "true science" and whether the absence of such a viable science in the sense expressed by Haskins will destroy our ability to manage and control the technology which science has helped to create, and which is essential to modern civilized life.'"

To a considerable extent your job and mine over the next few years will be to find the most effective ways to avoid the danger cited by Harvey Brooks at the same time that we implement the new targeted programs so desperately needed and wanted by our society as a whole.

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